**MAKING THE TRANSITION FROM COCs TO HRT:** (See Figure 26.5, p. 111)

## FERTILITY AFTER DISCONTINUATION OF METHOD

- Immediate return of fertility: Average delay in ovulation 1-2 weeks. Post-pill amenorrhea more common in women with a past history of very irregular menses; rarely persists for up to 6 months
- Women should initiate another method immediately after discontinuing COCs
- Women can be surprised to learn that their pattern of menses **prior** to starting pills (frequency, duration, flow, dysmenorrhea) **tends to return** once they stop COCs
- Taking pills for many years prior to trying to become pregnant may actually protect a woman from some of the causes of infertility such as endometriosis, endometrial cancer, uterine fibroids, polycystic ovarian disease and ovarian cancer

### Table 26.2 Starting Combined Oral Contraceptives*

| CONDITION BEFORE STARTING | WHEN TO START COCs? |
|---|---|
| Starting (restarting) COCs in menstruating women | • Immediately, if pregnancy excluded start with first pill in package; backup needed x 7 days<br>"QUICK START" *[Westhoff - 2002]* See p. 102<br>• First day of next menses<br>• If within 5 days after start of her menstrual bleeding, no backup required.**<br>• First Sunday after next menses begins.** Backup needed x 7 days |
| Starting (restarting) in amenorrheic women | Anytime if it is reasonably certain that she is not pregnant; abstain from sex or use backup method for next 7 days |
| Postpartum and breastfeeding | According to new CDC Medical Eligibility Criteria 2010, ← use of COCs in breastfeeding women is a category 2 at 1 month postpartum meaning advantages outweigh disadvantages*** |
| Postpartum and not breastfeeding (after pregnancy of 24 or more weeks) | • Wait 3 weeks after delivery to allow hypercoagulable state of pregnancy to abate |
| After 1st or 2nd trimester (≤ 24 weeks) pregnancy loss or termination | • Immediately - start the same day<br>No backup needed |
| Switching from another hormonal method | • Start COCs immediately if she has been using hormonal method correctly and consistently, or if it is reasonably certain she is not pregnant. No need to wait until next period. No additional contraceptive needed<br>• If previous method was an injectable, start COCs at the time repeat injection would have been given |
| Switching from a non-hormonal method (other than IUD) | • Can start immediately or at any other time if it is reasonably certain that she is not pregnant. Use backup method for the next 7 days unless it is the first day of menses |
| Switching from an IUD (including hormonal) | • Start pills within 5 days of start of mentrual bleeding, no additional contraceptive needed & IUD can be removed at that time<br>• Start pills at any other time if it is reasonably certain she is not pregnant. If sexually active in this menstrual cycle and more than 5 days since menstrual bleeding started, remove IUD at time of next menstrual period OR give EC, then start COCs immediately; backup x 7 days |
| After taking ECPs | • Day after ECP**<br>• First day of next menses } if using other interim<br>• Sunday of next menses** } method until menses |

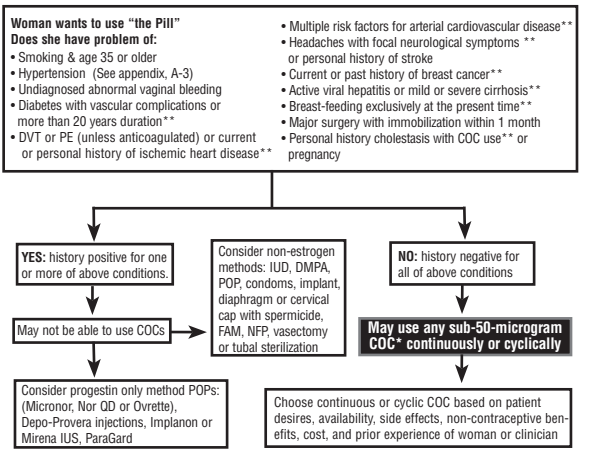
* World Health Organization. Selected Practice Recommendations for Contraceptive Use. 2004

** Back-up method needed for 7 days after starting COCs if it has been more than 5 days since menstrual bleeding started

*** CDC considering change to category 2 or 3 for the 3-6 week post partum period depending on a woman's risk factors for VTE.

**Figure 26.2**

## CHOOSING A PILL




- The World Health Organization and the Food and Drug Administration both recommend using the **lowest dose pill** that is effective. All combined pills with less than 50 µg of estrogen are considered "low-dose" and are effective and safe
- There are no studies demonstrating a decreased risk for deep vein thrombosis (DVT) in women on 20-µg pills. Data on higher dose pills have demonstrated that the less the estrogen dose, the lower the risk for DVT
- All COCs lower free testosterone. Class labeling in Canada for all combined pills states that use of pills may improve acne
- To minimize discontinuation due to spotting and breakthrough bleeding, warn women in advance, reassure that spotting and breakthrough bleeding become better over time. (See Figure 26.3, p. 109)

*The package insert for women on Yasmin and Yaz states *[Berlex-2001]*: "Yasmin is different from other birth control pills because it contains the progestin drospirenone. Drospirenone may increase potassium. Therefore, you should not take Yasmin if you have kidney, liver or adrenal disease, because this could cause serious heart and health problems. Other drugs may also increase potassium. If you are currently on daily, long-term treatment for a chronic condition with any of the medications below, you should consult your healthcare provider about whether Yasmin is right for you, and during the first month that you take Yasmin, you should have a blood test to check your potassium level: NSAIDs (ibuprofen [Motrin®, Advil®], naproxen [Naprosyn®, Aleve®, and others] when taken long-term and daily for treatment of arthritis or other problems]; potassium-sparing diuretics (sprironolactone and others); potassium supplementation; ACE inhibitors (Capoten®, Vasotec®, Zestril® and others); Angiotensin-II receptor antagonists (Cozaar®, Diovan®, Avapro® and others); heparin"

**These are conditions that receive a CDC:3 or a CDC: 4 (See appendix pages A-5 and A-7)

**Figure 26.3**

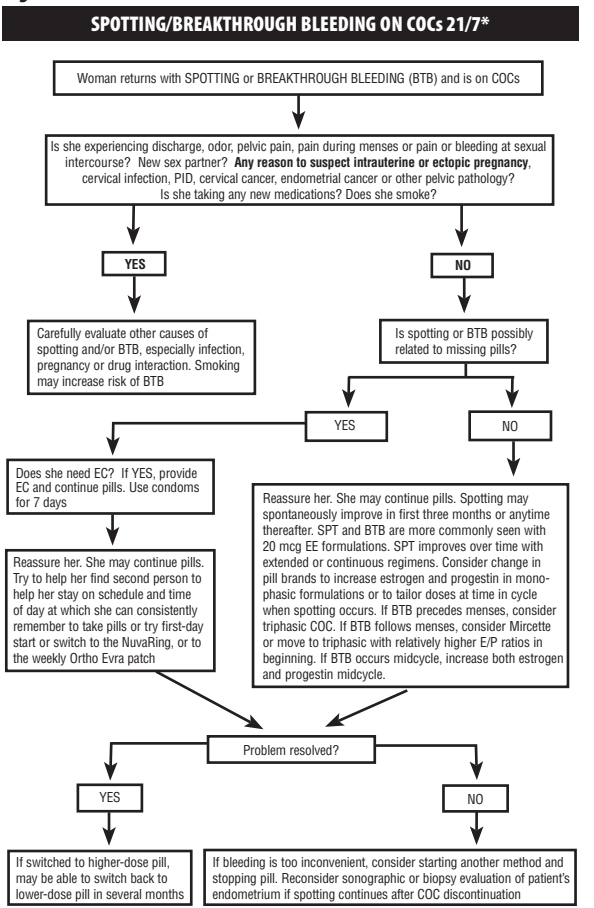

SPOTTING/BREAKTHROUGH BLEEDING ON COCs 21/7*
Woman returns with SPOTTING or BREAKTHROUGH BLEEDING (BTB) and is on COCs
Is she experiencing discharge, odor, pelvic pain, pain during menses or pain or bleeding at sexual intercourse? New sex partner? Any reason to suspect intrauterine or ectopic pregnancy, cervical infection, PID, cervical cancer, endometrial cancer or other pelvic pathology? Is she taking any new medications? Does she smoke?
YES
NO
Carefully evaluate other causes of spotting and/or BTB, especially infection, pregnancy or drug interaction. Smoking may increase risk of BTB
Is spotting or BTB possibly related to missing pills?
YES
NO
Does she need EC? If YES, provide EC and continue pills. Use condoms for 7 days
Reassure her. She may continue pills. Try to help her find second person to help her stay on schedule and time of day at which she can consistently remember to take pills or try first-day start or switch to the NuvaRing, or to the weekly Ortho Evra patch
Reassure her. She may continue pills. Spotting may spontaneously improve in first three months or anytime thereafter. SPT and BTB are more commonly seen with 20 mcg EE formulations. SPT improves over time with extended or continuous regimens. Consider change in pill brands to increase estrogen and progestin in mono-phasic formulations or to tailor doses at time in cycle when spotting occurs. If BTB precedes menses, consider triphasic COC. If BTB follows menses, consider Mircette or move to triphasic with relatively higher E/P ratios in beginning. If BTB occurs midcycle, increase both estrogen and progestin midcycle.
Problem resolved?
YES
NO
If switched to higher-dose pill, may be able to switch back to lower-dose pill in several months
If bleeding is too inconvenient, consider starting another method and stopping pill. Reconsider sonographic or biopsy evaluation of patient's endometrium if spotting continues after COC discontinuation

**Figure 26.4**

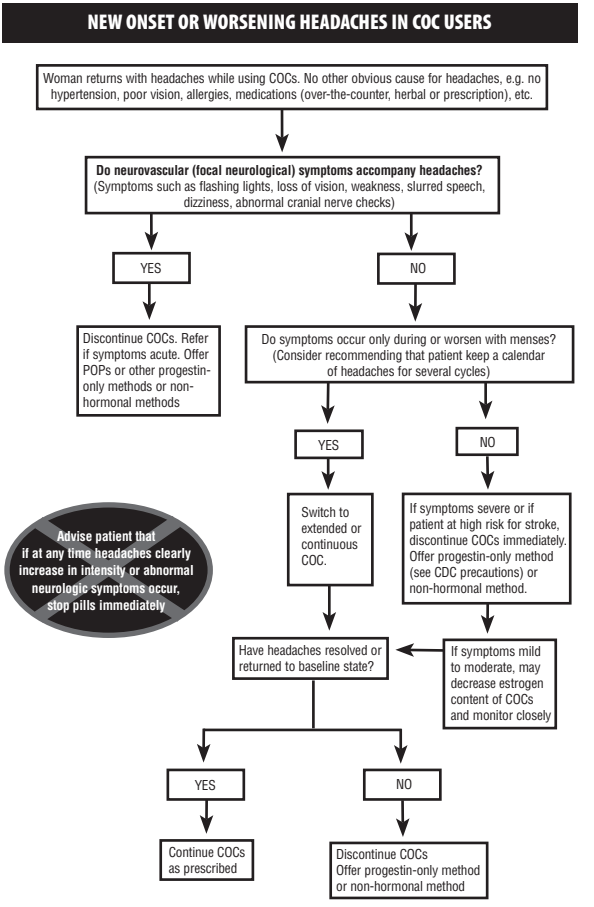
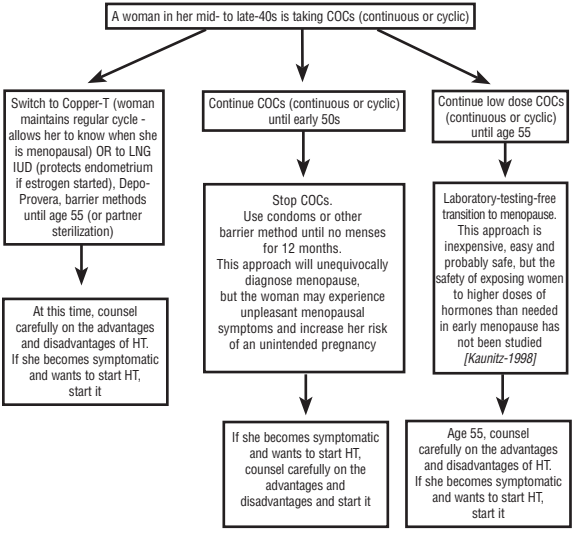

NEW ONSET OR WORSENING HEADACHES IN COC USERS
Woman returns with headaches while using COCs. No other obvious cause for headaches, e.g. no hypertension, poor vision, allergies, medications (over-the-counter, herbal or prescription), etc.
Do neurovascular (focal neurological) symptoms accompany headaches? (Symptoms such as flashing lights, loss of vision, weakness, slurred speech, dizziness, abnormal cranial nerve checks)
YES
NO
Discontinue COCs. Refer if symptoms acute. Offer POPs or other progestin-only methods or non-hormonal methods
Do symptoms occur only during or worsen with menses? (Consider recommending that patient keep a calendar of headaches for several cycles)
YES
NO
Switch to extended or continuous COC.
If symptoms severe or if patient at high risk for stroke, discontinue COCs immediately. Offer progestin-only method (see CDC precautions) or non-hormonal method.
Advise patient that if at any time headaches clearly increase in intensity or abnormal neurologic symptoms occur, stop pills immediately
Have headaches resolved or returned to baseline state?
If symptoms mild to moderate, may decrease estrogen content of COCs and monitor closely
YES
NO
Continue COCs as prescribed
Discontinue COCs Offer progestin-only method or non-hormonal method

**Figure 26.5**

## MAKING THE TRANSITION FROM COCs TO MENOPAUSE, WITH OR WITHOUT HORMONE THERAPY (HT)

*The transition from COCs to menopause, with or without HT may be accomplished in a number of ways. Some reviewers of this algorithm switch to a 20 or 25-mcg pill if the patient is going to use COCs into their early 50s. A major concern is unintended pregnancy. Work together to determine a method for pregnancy prevention that is acceptable and effective*

*This algorithm does NOT include testing for a woman's menopausal status using FSH or LH tests**




*FSH and LH testing are problematic because they show current status only. A perimenopausal woman can seem to be menopausal according to lab tests but ovulate unpredictably after that. See precautions about the provision of hormones to menopausal women on p. 24.

## PATCHES - WEEKLY - ORTHO EVRA PATCH

**DESCRIPTION:** One Ortho Evra patch is worn for one week for each of 3 consecutive weeks, on the lower abdomen, buttocks, upper outer arm or to the upper torso (except for the breasts). The fourth week is patch-free to permit withdrawal bleeding. This 4.5 cm square patch delivers 20 micrograms of ethinyl estradiol and 150 mcg of the progestin, norelgestromin (the active metabolite of norgestimate) daily. *[Grimes-2001]* It takes 3 days to achieve steady states or plateau levels of hormones after application of the patch and the patch contains sufficent hormone for 9 days though prescribing info states to remove after 7 days. The patch delivers about 60% more estrogen over a 21-day period than a 35 mcg EE COC and 3 times more than the ring

**MECHANISM:** The patch prevents pregnancy in the same manner as combined pills

**COST:** 3 patches are slightly more expensive than one cycle of brand pills

**EFFECTIVENESS:** Among perfect users (users who apply transdermal contraceptive patches on schedule and each patch remains in place for the full week), only 3-6 in 1,000 women (0.3-0.6%) are expected to become pregnant during the first year (Table 13.2 on p. 40). Pooled data from three contraceptive efficacy studies (22,155 treatment cycles) using life table analysis found an overall failure rate of about 1% (0.8% or 8 pregnancies per 1000 women through 13 cycles). *[Zieman-2001]*

Of 15 pregnancies in the 3 clinical trials of the Ortho Evra Patch, 5 were in women who were markedly overweight (women more than 90 kilograms or 198 pounds). *[Zieman-2001]* (30% of failures in 3% of women) There are no reliable data available about typical failure rates, thus the typical failure rate is presumed similar to COCs *[Audet-2001]*

### ADVANTAGES

***Menstrual:*** Like combined pills

***Sexual/Psychological:***

- May enhance sexual enjoyment due to diminished fear of pregnancy
- Attractive for women who forget to take pills
- Does not interrupt intercourse

***Cancers/tumors and masses:*** No data yet; benefits probably comparable to combined pills

***Other:***

- Option throughout the reproductive years: Age is not a reason to avoid the Patch. Compliance among teens using patch is good. For some women compliance may be easier than taking a pill every day *[Audet-2001]*. Each patch contains enough hormone to suppress ovulation for up to 9 days.
- May bathe, swim and do normal activities

### DISADVANTAGES

***Menstrual:*** In the first cycle, about one-fifth of patch users experienced breakthrough bleeding or spotting. This improved with time

***Sexual/Psychological:*** Similar to pills, but use may be more obvious than pills. See p. 95

***Cancers/tumors and masses:*** Same as COCs

***Other:***

- Lack of protection against sexually transmitted infections (STIs)
- Among 812 women on the patch, 3 serious adverse events were considered possible or likely related to use of the patch, including 1 case of pain and paraesthesia in the left arm, 1 case of migraine and 1 case of cholecystitis *[Audet-2001]*

- Must remove and replace patch weekly. Application site problems include partial detachment (2.8%) or complete detachment (1.8%) and skin irritation (1.1%) *[Audet-2001].* **Pigment changes (hyper and hypo) have been noted under the site of patch application.** In a study of patch wear under conditions of physical exertion and variable temperatures and humidity, less than 2% of patches were replaced for complete or partial detachment. 2.6% of women discontinued using the patch because of application site reactions. Problems did not increase over time *[Audet-2001].* Border of patch may become dirty, picking up lint, hairs or fabric. Able to remove with baby oil after patch is changed
- Nausea occurred in 20.4% of women on patch vs 18.3% of women using oral contraceptives; patch was discontinued by 1.8% of women because of nausea *[Audet-2001]*
- Breast discomfort was greater in women using the patch than in women on the pill. The difference was significant only in cycles 1 and 2 (15.4% vs 3.5% in cycle 1 and 6.6% vs 1.5% in cycle 2). For cycles 3-13, breast discomfort occurred in 0 to 3.2% of women using the patch and in 0 to 1.7% of women on pills (not statistically significant) *[Audet-2001]*
- Headaches were as likely in women on patch (21.9%) as in women on pills (22.1%)
- Irritation or an allergic skin reaction while using the patch (19%)

## COMPLICATIONS (See p. 114)

- Data demonstrate that patch users had average concentrations of EE at steady state that were ~60% higher than women using COCs with 35 mcg EE. They also had ~25% lower peak levels of EE. Based on data from oral contraceptives, higher levels of estrogen are associated with an increased risk of VTE and CV events. Epidemiologic data on the patch are limited so far. Several case control studies have reported odds ratios for VTE ranging from 0.9 to 2.4 meaning that there may be no increased risk or an approximate doubling of risk *[Jick-2006, 2007 Package Insert] [Cole-2007].* Currently available data do not show an increased risk of MI or stroke. Women choosing the patch should be informed of **the possiblity** of an increase in risk of adverse events, particularly VTE.
- Other complications similar to COCs

## PRESCRIBING PRECAUTIONS

- Precautions for the patch are the same as those for combined pills (see p. 108 and A1-A8)
- **Women weighing more than 90 kg (198 lbs)** should be told that the patch is less effective as compared to its use in women < 198 lbs and that they should consider using a backup or another method. Should not be a "first-line" method for woman over 198 pounds

## CANDIDATES FOR USE

- Women wanting to avoid daily pill-taking or a sex-related method like condoms
- Women wanting regular menstrual periods. May be used by individuals allergic to latex

***Adolescents:*** **Excellent option, particularly for teenage women unable to remember to take pills daily** *[Archer-2002]*

## INITIATING METHOD

- With the 1st pack of patches, the patient is eligible for up to three free replacement patches. Write prescription for "replacement patch" with the first box of patches
- **A pelvic examination is not necessary prior to starting this method** *[Stewart-2001]*
- Ask patient, "What day of the week is the easiest for you to remember?" and start then if you are reasonably certain she is not pregnant. Unlike pills, the time of day doesn't matter!
- Women switching from pills can switch to the patch any time in cycle. They need not wait to complete pack of pills
- Women switching from DMPA should start when the next injection is due
- But as with pills, the patch can be started anytime with backup for 7 days, if you are reasonably sure the woman is not pregnant. If started on day one of cycle, backup not needed
- Quick Start initiation of the patch resulted in no increase in pregnancy or BTB *[Murthy-2005]*
- Provide or recommend EC for when/if needed

**INSTRUCTIONS FOR PATIENT**

- If the PATCH-FREE interval is more than 9 days (late restart), apply a new patch and use backup contraception for 7 days
- No band-aids, tatoos, or decals on top of patch as this might alter absorption of hormones
- Smooth the edges down when you first put it on
- Avoid placing patch on exactly the same site 2 consecutive weeks
- Location of patch should not be altered in mid-week
- Women should check the patch daily to make sure all edges remain closely adherent to skin
- Single replacement patches are available through pharmacists. The manufacturer will reimburse a woman for up to $12 for the replacement patch
- Disposal: fold over self. Place in solid waste, preferably in a sealed plastic bag to minimize hormone leakage into waste site. Do not flush down toilet

**FOLLOW UP**

- What is happening to your menstrual periods?
- Have you experienced skin irritation?
- Has your patch ever come off partially or completely?
- Have you had problems remembering to replace your patch on schedule

**PROBLEM MANAGEMENT** (See p. 106)

**FERTILITY AFTER DISCONTINUATION OF METHOD:** Likely the same rapid return of fertility as COCs

## VAGINAL CONTRACEPTIVE RING - MONTHLY - NuvaRing

**DESCRIPTION:** (also see www.nuvaring.com) The NuvaRing is a combined hormonal contraceptive consisting of a 5.4 cm (2 inches) diameter flexible (not hard) ring, 4 mm (1/8 inch) in thickness. The ring is made of ethylene vinylacetate polymer. It is left in place in the vagina for 3 weeks (or 1 month) and then removed for a week to allow withdrawal bleeding. It may be used continuously with no hormone-free days, but this is off-label. **It is generally recommended that it not be removed for intercourse. If it must be, however, it should be replaced within 3 hours.** Douching is discouraged but topical therapies (antifungal agents, spermicides, etc) are allowed. NuvaRing releases low doses of ethinyl estradiol (15 micrograms daily) and etonogestrel, the active form of desogestrel (120 micrograms daily). With oral hormones there is a daily spike in hormone levels after the woman swallows each dose, followed by a gradual drop throughout the rest of the day. A single vaginal ring maintains a steady, low release rate for 35 days while in place and releases less estrogen daily at a steadier rate than pills or patches

**HOW CONTRACEPTIVE VAGINAL RINGS WORK:** ***contraceptive effects similar to combined pills.*** This method suppresses ovulation for 35 days, while in place *[Mulders-2001]*. Also see COCs, p. 94

**COST:** Each ring costs approximately the same as one cycle of pills. It is possible to get some free rings via the website at www.nuvaring.com. Public health programs pay much less for each NuvaRing

**EFFECTIVENESS:** Overall pregnancy rate of 0.3 *[Trussell-2004]* to 0.65 *[Roumen-2001]* per 100 woman-years (all first-year users). There is no information about typical use failure rate, so a typical use failure rate of 9% is used by Trussell in the 18th edition of ***Contraceptive Technology*** (same figure as for combined pills). It is likely that since the method needs to be remembered once per month rather than once per day, that the typical user failure rate would be lower

**ADVANTAGES: No daily fluctuation in hormone levels**

***Menstrual:***

- Withdrawal bleeding occurs in 98.5% of cycles, and bleeding at other times in only 5.5% of cycles *[Dieben-2002]*; much better withdrawal/spotting pattern than COCs probably due to NOT forgetting pills and the steady even blood levels that are achieved
- Irregular bleeding is low in the first cycle of use (6%) and continues to be low throughout subsequent cycles *[Dieben-2002]*

***Sexual/Psychological:*** Decreased fear of pregnancy may increase pleasure from intercourse

***Cancers/tumors and masses:*** No published data; probably similar to COCs

***Other:*** There are only 2 tasks for ring users to remember: insertion and removal once a month so compliance may be easier (92% vs. 75% for pills in one study) *[Bjarnadottir-2002]*

- 85% of women and 71% of partners say they cannot feel it *[Dieben-2002]*
- The lowest serum levels of estrogen and progestin in any combined hormonal method
- Privacy - no visible patch or pill packages. Particularly helpful for some teens
- Little weight gain associated with ring use *[O'Connel-2005]*

**DISADVANTAGES**

***Menstrual:*** Withdrawal bleeding continued beyond the ring-free interval in about one quarter of cycles (20% to 27%) *[Roumen-2001]*. However, most of the time it is just spotting. Although not necessary, some women may rinse the ring. Also, ring can be accidentally pulled out by a tampon

***Sexual/Psychological:*** Some women dislike placing/removing objects into/out of vagina Some women or men may feel ring during intercourse. If bothersome, ring may be removed and reinserted within 3 hours

***Cancers/tumors and masses:*** None

***Other***: Adverse events reported by vaginal contraceptive ring users that were judged by the investigators to be possibly device related are headache (6.6%), nausea (2.8%), weight increase (2.2%), dysmenorrhea (1.8%), depression (1.7%), leukorrhea (5.3%), vaginitis (5.0%), and vaginal discomfort (2.2%) *[Roumen-2001]*

**COMPLICATIONS:** Similar to combined pills

**PRESCRIBING PRECAUTIONS**

- The CDC Medical Eligibility Criteria for the NuvaRing are the same as for combined pills
- Women who are hesitant about touching their genitalia or who have difficulty inserting or removing ring may not be good candidates
- Women with pronounced pelvic relaxation

**CANDIDATES**

- Women wanting to avoid having to do something daily, or at the time of intercourse
- Women wanting regular menstrual periods
- Women satisfied with OCs but willing to try the patch or ring were happier with the ring than their OC *[Creinin-2007]*

***Adolescents:*** Excellent option; requires less discipline than taking pills daily

**INITIATING METHOD:** ***Best approach - teach women to insert and remove ring in office. Ask women if they would like you to insert a ring after you do an exam to demonstrate just how little she will feel the ring***

- A new ring is inserted any time during the first 5 days of a normal menstrual cycle and backup for 7 days is recommended in package insert
- New ring can be inserted at any time in cycle if reasonably certain woman is not pregnant; use backup x 7 days (CDC)
- Provide or recommend EC for when/if needed
- Quick Start of Nuvaring has been studied with high levels of satisfaction by users *[Schafer-2006].* See p. 102 for description

**INSTRUCTIONS FOR PATIENT**

- The package insert states that backup must be used during the first 7 days that the first ring is in place
- The NuvaRing is removed at the end of 3 weeks of wear; then, after one ring-free week, the woman inserts a new ring
- The woman's menstrual period (withdrawal bleed) occurs during the ring-free week
- Ring removal during intercourse is not recommended; however, women who want to remove it during intercourse may do so without having to use a backup method as long as it is not removed for longer than 3 hours a day
- Although it is intended to be a once a month method, check for presence frequently, especially after intercourse since 20% of women experience expulsion in the first 3 months
- No special accuracy is required for ring placement; absorption is fine from anywhere in the vagina
- Because the ring is small and flexible, **most women do not notice any pressure or discomfort**, and it is not likely to be uncomfortable for their partners during intercourse
- Always have 2 rings on hand in case one is lost
- Avoid douching with ring in place. Douching is not recommended for any woman
- Tampons, lubricants and vaginal yeast creams can be used with the ring in place
- Rings may be stored at room temperature avoiding extreme heat for up to 4 months. If a woman has more than a 4-month supply of rings, they may be stored in a refrigerator. Rings kept in a refrigerator should not freeze
- A ring that falls into the toilet does float! It can be washed with soap and water and reinserted
- If the ring is left in place longer than three weeks, the user is probably still protected from pregnancy for up to 35 days by the same ring, allowing clinicians flexibility in how often they tell women the ring must be replaced. For example, the ring could be reinserted on the first of the month each month with no hormone-free interval (similar to taking combined pills with no hormone-free days)
- Extended use of the ring has been studied. The number of bleeding and spotting days combined was similar in shorter and extended cycles *[Miller-2005].* Extended use decrease menstural flow and cramping *[Sulak-2008].* If breakthrough bleeding occurs, instruct the patient to remove the ring, store it for 4 days, then reinsert *[Sulak-2008]*
- **Dispose of ring with solid waste, preferably in a sealed plastic bag to minimize leakage into waste site**

**FOLLOW UP:** Ask about difficulty during removal or insertion or frequent expulsion. Women may need closer follow-up if they have: genital prolapse, severe constipation, or frequent vaginal infection (i.e. recurrent yeast infection). Otherwise, similar to women on pills

**FERTILITY AFTER DISCONTINUATION:** Excellent and immediate. Average return to ovulation: 11 days (range 8-21 d) *[Mulders-2002]*

# CHAPTER 25

# Progestin-Only Contraceptives

www.managingcontraception.com

The progestin-only methods are progestin-only pills (p. 117), Depo-Provera (p. 121), and Implanon (p. 130). The LNG IUD is described on p. 90

## LOW DOSE PROGESTIN PILLS - DAILY - often called MINI-PILLS OR POPS

**DESCRIPTION:** Progestin-only pills (POPs) are also known as mini-pills. POPs contain only a progestin and are taken daily with no hormone-free days. POPs have lower progestin doses than combined pills and no estrogen. Each tablet of Micronor and Nor-QD contains 0.35 mg norethindrone.

**EFFECTIVENESS** *[Trussell J IN Contraceptive Technology 2004]*
***Perfect use failure rate in first year:*** 0.3% (See Table 13.2, p. 40)
(if 300 women take POPs for 1 year, only 1 will become pregnant in the first year of perfect use)
***Typical use failure rate in first year:*** 8.0%

**HOW POPs WORK:** Thickens cervical mucus to prevent sperm entry into upper reproductive tract (major mechanism). Effect short lived - requires punctual dosing. Other mechanisms include ovulation suppression (in about 50% of cycles), thin, atrophic endometrium which inhibits implantation; and slowed sperm motility. Some POPs in Europe suppress ovulation more than the norethindrone pills used in the USA

**COST** *[Trussell, 1995; Smith, 1993]*
- POPs cost more than combined pills both in pharmacies and in sales to public programs

**ADVANTAGES**

***Menstrual:***
- Decreased menstrual blood loss, cramps and pain, amenorrhea (10% of women). Amenorrhea is more likely with punctual dosing
- Decrease in ovulatory pain (Mittelschmerz) in cycles when ovulation suppressed

***Sexual/physiological:***
- May enhance sexual enjoyment due to diminished fear of pregnancy
- No disruption at time of intercourse; facilitates spontaneity

***Cancers, tumors and masses:***
- Possible protection against endometrial cancer

***Other:***
- Rapid return to baseline fertility
- Possible reduction in PID risk due to cervical mucus thickening
- Good option for women who cannot use estrogen but want to take pills
- May be used by smokers over age 35. **Discourage smoking, of course!**
- May be used by breastfeeding women

## DISADVANTAGES

***Menstrual:*** Irregular menses ranging from amenorrhea to increased days of spotting and bleeding but with reduced blood loss overall

***Sexual/psychological:***

- Spotting and bleeding may interfere with sexual activity
- Intermittent amenorrhea may raise concerns about pregnancy
- Possible increase in depression, anxiety, irritability, fatigue or other mood changes, but often POPs reduce risk of these disorders

***Cancers, tumors and masses:***

- May be associated with slightly higher risk of persistent ovarian follicles

***Other:***

- Must take pill at same time each day (more than 3-hour delay considered by some clinicians to be equivalent to a "missed pill")
- Effect on cervical mucus decreases after 22 hours and is gone after 27 hours
- No protection against STIs

## COMPLICATIONS

- Allergy to progestin pill is rare
- Amenorrheic, Latina, breast-feeding women who had gestational diabetes may be at higher risk of developing overt diabetes in first year postpartum *[Kjos, 1998]*

## CANDIDATES FOR USE (See 2010 CDC Medical Eligibility Criteria, A-1 - A-8)

- Virtually every woman who can take pills on a daily basis can be a candidate for POPs
- POPs are particularly good for women with contraindications to or side effects from estrogen:
  - Women with personal history of thrombosis
  - Recently postpartum women
  - Women who are exclusively breast-feeding
  - Smokers over age 35
  - Women who had or fear chloasma, worsening migraine headaches, hypertriglyceridemia or other estrogen-related side effects (e.g. nausea)
  - Women with hypertension, coronary artery disease or cerebrovascular disease
  - Women wth lupus

## PRESCRIBING PRECAUTIONS

Progestin-only pills can be used by all women willing and able to take daily pills except:

- Suspected or demonstrated pregnancy (although there are no proven harmful effects for the fetus)
- Current breast cancer or breast cancer less than 5 years ago (CDC:3)
- Active hepatitis, hepatic failure, jaundice
- Inability to absorb sex steroids from gastrointestinal tract (active colitis, etc.)
- Taking medications that increase hepatic clearance (rifampin, and the anticonvulsants carbamazepine, oxycarbazepine, phenytoin [Dilantin], phenobarbital, primidone, topiramate and felbamate, [not valproic acid], St. Johns Wort or griseofulvin). Efficacy in combination with Orlistat and other fat-binding agents is not well studied

**MEDICAL ELIGIBILITY CHECKLIST: Evidence-based criteria for deciding whether women with 130 different conditions are presented in the appendix, pages A-1 through A-8. These criteria were updated at the World Health Organization in 2004.** Ask the client the questions below. If she answers YES to a question below, follow the instructions; in some cases she can still use POPs

***1. Do you think you are pregnant?***

☐ No ☐ Yes Assess if pregnant. If she might be pregnant, give her latex male condoms to use until reasonably sure that she is not pregnant. Then she can start POPs

***2. Do you have or have you ever had breast cancer? (See Appendix)***

☐ No ☐ Yes Do not provide POPs. Help her choose a method without hormones. May possibly consider POPs or DMPA if disease-free x 5 years (CDC:3), but only if there is no better alternative

***3. Do you have jaundice, severe cirrhosis of the liver, acute liver infection or tumor? (Are your eyes or skin unusually yellow?) (See Appendix)***

☐ No ☐ Yes Perform physical exam and arrange lab tests or refer. If she has serious active liver disease (jaundice, painful or enlarged liver, viral hepatitis, liver tumor), may be able to use POPs with more intensive follow-up (CDC:3)

***4. Do you have vaginal bleeding that is unusual for you? (See Appendix)***

☐ No ☐ Yes If she is not pregnant but has unexplained vaginal bleeding that suggests an underlying medical condition, can provide POPs since neither the underlying condition nor its assessment will be affected. Promptly assess and treat any underlying condition as appropriate, or refer. Reassess POP use based on findings

***5. Are you taking medicine for seizures? Taking rifampin (rifampicin), griseofulvin or aminoglutethimide? St. Johns Wort? (See Appendix)***

☐ No ☐ Yes If she is taking phenytoin, carbamazepine, barbiturate, topiramate, oxycarbamazepine, or primidone for seizures or rifampin, griseofulvin, aminoglutethamide or St. John's Wort, provide condoms or spermicide or help her choose another method that is more effective, such as DMPA. Use of valproic acid does NOT lower the effectiveness of POPs. Discuss ECPs

***6. Do you have problems with severe diarrhea or malabsorption or other bowel disorders? Or are you using medications that block fat absorption?***

☐ No ☐ Yes Help her choose a non-oral method of birth control.

## SPECIAL SITUATIONS

***History of pregnancy while using POPs correctly:***

- Switch to more effective method e.g. IUD, Implanon or DMPA
- Continue POPs but add condoms or other backup with every act of coitus

***Use with a broad-spectrum antibiotic such as tetracycline or erythromycin:***

- Few studies support antibiotic's role in contraceptive failure. See 2010 CDC Medical Eligibility Criteria for "other antibiotics," CDC:1, Page A8. Some clinicians encourage backup for first 1-2 weeks, others for full duration of antibiotic use. Explain conflicting advice now being given; let patient decide whether to use backup method.

## INITIATING METHOD

- **A pelvic examination is not necessary prior to initiation of this method** *[Stewart-2001]*
- ***New starts:*** Offer condoms either for back-up for 2 days or for use should patient stop POPs. Also encourage advance obtaining of PLAN B or give her a package of PLAN B
- ***Post-partum:*** May initiate immediately regardless of breast-feeding status (PPFA, UCSF, Grady Memorial Hospital)
  ***Note:*** CDC and IPPF are concerned about theoretical impact of POPs on breast milk production and recommend waiting until 6 weeks to initiate use of DMPA and POPs
- ***After miscarriage or abortion:*** Start immediately
- ***Menstruating women:*** Start on menses if possible. No backup if started within 5 days of LMP. May initiate anytime in cycle if woman is not pregnant, but recommend at least 2 day back-up barrier method
- ***Switching from IUD, COCs, DMPA, to POPs:*** Start immediately. Need for back-up depends on previous method used: **IUD:** start immediately, backup for 7 days; Some clinicians say 48 hours minimum; others say no backup. **COCs:** start immediately if cycle of hormonally active pills completed; backup not necessary if no pill-free interval. **DMPA:** start immediately if switching at or before next DMPA injection due (no backup necessary)

## INSTRUCTIONS FOR PATIENT

- Take one pill daily at same time each day until end of pack. Start next pack the next day
- If at risk for infection, use condoms with every act of intercourse
- If you miss a pill by more than 3 hours from regular time, take the missed pill(s) and use backup for 48 hours. Consider using emergency contraception if sex in past 5 days. Obtain a package of Plan B to have at home in case of a mistake

## FOLLOW-UP

- How many pills do you typically miss or are late taking per week? Per pack?
- Have you missed any pills in last 5 days? (candidate for EC)
- Have you missed any periods or experienced any symptoms of pregnancy?
- What has your menstrual bleeding been like?
- Have you had any increase in headaches, or change in mood or libido?
- Do you plan to have children? OR Do you plan to have more children?
- What are you doing to protect yourself from STIs?

## PROBLEM MANAGEMENT

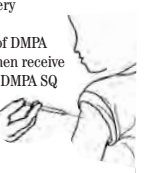
- ***Amenorrhea:*** Rule out pregnancy with first episode or whenever symptoms of pregnancy noted. Otherwise, amenorrhea is not harmful when women take progestin-only pills
- ***Irregular bleeding:*** After finding out if missing pills, rule out STIs, pregnancy, cancer. If not at risk and no evidence of underlying pathology, reassure patient; 3-day course of high dose NSAIDS may help
- ***Heavy bleeding:*** Rule out STIs, pregnancy, cancer. If no evidence of underlying pathology, rule out clinically significant anemia. Trial of 3 days high dose NSAIDS. If fails, may need estrogen-containing contraceptives (addition of physiologic doses ET only may compromise cervical mucus barrier), Mirena IUS or non-hormonal methods of contraception
- A***bdominal pain:*** Consider pelvic pathology (ectopic pregnancy, torsion, appendicitis, PID) and refer for treatment. If ovarian cyst is cause, it may usually be managed conservatively unless pain is severe. Progestin slows follicular atresia. Recheck in 6 weeks and anytime her symptoms worsen

**FERTILITY AFTER DISCONTINUATION OF METHOD:** Fertility returns to its baseline levels promptly

## DMPA INJECTIONS (DEPO-PROVERA) - EACH 3 MONTHS

**DESCRIPTION:** 1 cc of a crystalline suspension of 150 mg depot medroxyprogesterone acetate injected intramuscularly into the deltoid or gluteus maximus muscle every 13 weeks For more information, call 1-800-253-8600 ext. 38244.

Depo-Provera Subcutaneous - 104, subcutaneous injections of 104 mg of DMPA facilitate women giving themselves Depo-Provera injections at home. Women receive up to 14 weeks of contraceptive protection from an injection of 104 mg of DMPA SQ



**EFFECTIVENESS** *[Trussell J IN Contraceptive Technology - 2004]*

- Approved labeling indicates each injection effective for up to 13 weeks

***Perfect use failure rate in first year:*** 0.3% (See Table 13.2, p. 40)
***Typical use failure rate in first year:*** 3%
***Continuation at 1 year:*** 23% *[Westfall-1996]* 42% *[Polaneczky-1996]* 56% *[Trussell-2004]*

**Subcutaneous Depo-Provera**

Despite the lower dose of Sub Q DMPA (104 vs 150 mg), no pregnancies occurred among the 44% of study subjects who were overweight (26%) or obese (18%). In fact, there were no pregnancies at all in 720 women over one year. 55% were amenorrheic at the end of one year. *[Jain J, Jakimiuk AJ et all-2004]*

**HOW DEPO WORKS:** Suppresses ovulation by inhibiting LH and FSH surge, thickens cervical mucus blocking sperm entry into female upper reproductive tract, slows tubal and endometrial mobility, and causes thinning of the endometrium

**COST:** In Washington State, health departments pay $4.75 for 28 days of contraception for a woman receiving Depo-Provera each 3 months. This is 4 times greater than the cost of pills for the same clinics, $1.35 per cycle. *[Margulies - 2001]* The co-pay for DMPA is about $60/vial

### ADVANTAGES

***Menstrual:***

- Less menstrual blood loss, anemia, or hemorrhagic corpus luteum cysts
- After 1 year of use, 50% of women develop amenorrhea; 80% develop amenorrhea in 5 years. For this to be an advantage, it must be clearly explained at first and subsequent visits. See discussion of structured counseling on page 13
- Decreased menstrual cramps, pain and ovulation pain
- Improvement in endometriosis. ***Depo-Provera Subcutaneous 104*** was also FDA approved for management of endometriosis pain on March 29, 2005

***Sexual/psychological:***

- Intercourse may be more pleasurable without worry of pregnancy
- Convenient: permits spontaneous sexual activity; requires no action at time of intercourse

***Cancers, tumors, and masses:***

- Significant reduction in risk of endometrial cancer
- Possible reduction in risk of ovarian cancer

***Benefits for women with medical problems:***

- Suppresses ovulation, bleeding and menstrual blood loss in anticoagulated women and women with bleeding diathesis; decreases anemia
- Reduces acute sickle cell crises by 70% *[de Abood-1997]*
- Excellent method for women on anticonvulsant drugs; **may actually decrease seizures** and effectiveness not compromised
- Amenorrhea and prolonged effective contraception may be very important for severely developmentally or physically challenged women. One reviewer makes home visits for some wheelchair bound patients who love Depo-Provera

***Other:***

- The drop in teen pregnancies in 1990s, abortions and births, is attributed to Depo-Provera, Norplant, EC, condoms and abstinence promoting programs
- Significantly reduces risk for ectopic pregnancies and slightly decreases risk of PID
- Convenient: single injection provides at least 13 weeks protection
- Most protocols call for administration anytime between 11 and 13 weeks. However, DMPA is usually forgiving of late injections
- Less user-dependent than POPs, COCs
- Good option for women who cannot use estrogen (see CANDIDATES FOR USE)
- Private: no visible clue that patient is using except for impact on menses
- May be used by nursing mothers
- Return to baseline fertility may be delayed, but is excellent

## DISADVANTAGES

***Menstrual:***

- Irregular menses during first several months: many women experience unpredictable spotting and bleeding, occasionally blood loss reported to be heavy but unlikely to cause anemia. After 6-12 months, amenorrhea more likely (50% after 1 year)

***Sexual/psychological:*** Also see weight gain, below

- Spotting and bleeding may interfere with sexual activity
- Amenorrhea may raise patient's fears of pregnancy or myth of "build-up of menses" in uterus if not explained well
- Hypoestrogenism can (infrequently) cause dyspareunia, hot flashes or decreased libido
- Possible increase in depression, anxiety, irritation, PMS, fatigue or other mood changes, but often DMPA reduces risk of these disorders
- Fear of needles may make this an unacceptable choice

***Cancers, tumors, and masses:*** none

***Other:*** (See boxed message: Depo Provera & Bones on p. 123)

- No protection against STIs: must use condoms if at risk
- Must return every 11-13 weeks for injection (difficult for some women) or get injection from person trained to provide injections
- Long acting: ***not*** immediately reversible
- Slow to return to baseline fertility: average 10 months from last injection
- Occasionally, hypoestrogenism ($E_2 < 25$) may develop as a result of FSH suppression. Potential for decreased bone mineral density if used for prolonged period without opportunity for recovery prior to menopause. May have more effect on teen bones. See box on p. 123
- Severe headaches may occur - rarely attributable to DMPA
- Acne, hirsutism may develop
- Possible increase in diabetes risk in amenorrheic breastfeeding women with diagnosis of gestational diabetes during first year postpartum *[Kjos 1999]*
- Metabolic impacts: glucose (slight rise), LDL (slight rise or neutral), HDL (may decrease)
- Other hormone-related Sx: breast tenderness, bloating, hair loss, vasomotor symptoms
- Associated with modest weight gain in most women *[Westhoff-2007]* ←

## COMPLICATIONS

- Progressive significant weight gain possible. Average of 5.4 lbs in first year and 16.5 lbs after 5 yrs *[Schwallie-1973]* See p. 125: WEIGHT GAIN: A TEACHABLE MOMENT. Adolescent girls who were obese when starting Depo gained significantly more weight (mean 9.4 kg) than obese girls starting OCs (mean 0.2 kg) and controls (mean 3.5 kg) *[Ziegler-2006]*
- Worsening depression (rare) (average MMPI does not change in women on DMPA).
- Severe allergic reaction, including anaphylaxis (very rare). May consider having women wait in or near office for 20 minutes after injection. (Reviewers disagree about this recommendation, especially for previous DMPA users). Ask patients to report itching at injection site

**CANDIDATES FOR USE** (See new 2010 CDC Criteria on pages A-1 through A-8)

- Women who want intermediate-to-long-term contraception and can return every 11-13 weeks
- Women who do not plan a pregnancy soon after DMPA discontinuation
- Women who want privacy, convenience, and high efficacy
- Women who want or need to avoid estrogen:
  - Women with personal history of thrombosis (CDC: 2) or strong family history of venous thromboembolism (CDC: 1)
  - Recently postpartum women (CDC: 1)
  - Women who are exclusively breast-feeding beyond 6 weeks postpartum (CDC: 1). There is debate about use of DMPA in breastfeeding women less than 6 weeks PP (see p. 125 under INITIATING METHOD POSTPARTUM)
  - Smokers over age 35 (CDC: 1)
  - Women who fear chloasma or had vomiting, migraine headaches, hypertriglyceridemia, or other estrogen-related side effects
- Women who use drugs which affect liver clearance (except aminoglutethimide)
- Women with anemia, fibroids, seizure disorder (CDC 1), sickle cell disease (CDC: 1), endometriosis, hypertriglyceridemia (CDC: 2), systemic lupus erythematosus or coagulation disorder (hyper- or hypo-coagulation)
- Physically compromised women for whom bleeding is a nuisance or a problem

***Adolescent women:*** (CDC: 2) Only 4 things to remember to do each year!

- Extremely effective with long carry-over if patient returns late for reinjection (see Figure 27.1, p. 128); Decreases menstrual cramps and pain
- Does not protect against STIs
- Privacy and confidentiality possible
- For some teens may be only acceptable method
- May be associated with significant weight gain, acne, complexion changes
- Requires periodic reinjections

**Bone Mineral Density and Depo-Provera**

Depo-Provera received a black box warning from the FDA in 11/04 due to this issue. ACOG and AAP recommend no limit to use and no BMD testing. Some reviewers of this book think this was too severe a warning. All DMPA users should have the warning clearly explained to them and a discussion of alternatives if they choose to change methods. Women who used DMPA for more than 2 years have significantly reduced bone mineral density (BMD) of lumbar spine and femoral neck. But effect is largely reversible, even after $\geq$ 4 years of DMPA use, comparable to the effect and reversal seen after lactation *[Petitti-2000]*. **All women using DMPA including teens should be taking in sufficient calcium in diet or be encouraged to take calcium supplements. Also encourage to exercise regularly and avoid smoking.** Longitudinal studies of DMPA use in teens found a significant difference in BMD between DMPA users and non-users due to a decrease in users and an increase in nonusers. By 12 months after discontinuation, BMD of former users was the same as for non-users. *[Scholes-2005]*

**PRESCRIBING PRECAUTIONS:** **Women unwilling to accept a change in their menstrual periods**
- Pregnancy
- Undiagnosed abnormal vaginal bleeding
- Unable to tolerate injections; afraid of shots
- History of breast cancer, MI or stroke
- Current venous thromboembolism (unless anticoagulated)
- Active viral hepatitis
- Known hypersensitivity to Depo-Provera

**See previous page "Bone Mineral Density and Depo-Provera" about package insert black box warning**

**DRUG INTERACTIONS:** Aminoglutethimide (Cytodren), used to treat Cushings disease, reduces DMPA efficacy

## MEDICAL ELIGIBILITY CHECKLIST

Ask the client the questions below. If she answers NO to ALL the questions, then she CAN use DMPA if she wants. If she answers YES to a question below, follow the instructions

***1. Do you think you are pregnant?***

☐ No ☐ Yes Assess if pregnant. If she might be pregnant, give her condoms or spermicide to use until reasonably sure that she is not pregnant. Then she can start DMPA

***2. Do you plan to become pregnant in the next year?***

☐ No ☐ Yes Use another method with less potential delay in return of fertility

***3. Do you have serious medical problems such as heart attack, severe chest pain, or uncontrolled high blood pressure? Have you ever had such problems? (See Appendix)***

☐ No ☐ Yes In general, do not provide DMPA if she reports heart attack (CDC:3), stroke (CDC:3), heart disease due to blocked arteries, severe high blood pressure (systolic $\geq$ 160 or diastolic $\geq$ 100)(CDC:3), diabetes for more than 20 years (CDC:3), or damage to vision, kidneys, or nervous system caused by diabetes or by HTN. Help her choose another effective method. All the above conditions receive a "3" in the 2010 CDC Medical Eligibility Criteria

***4. Do you have or have you recently had breast cancer (CDC: 3 or 4)? (See Appendix)***

☐ No ☐ Yes Do not provide DMPA. Help her choose a method without hormones. If cancer-free for 5 or more years, a woman with a history of breast cancer may possibly use DMPA (CDC: 3)

***5. Do you have jaundice, cirrhosis of the liver, a liver infection or tumor? (Are her eyes or skin unusually yellow?) (See Appendix)***

☐ No ☐ Yes Perform physical exam or refer. If she has serious liver disease (jaundice, painful or enlarged liver, viral hepatitis, liver tumor), do not provide DMPA. Refer for care. Help her choose a method without hormones

***6. Do you have vaginal bleeding that is unusual for you? (See Appendix)***

☐ No ☐ Yes If she is not pregnant but has unexplained vaginal bleeding that suggest a serious underlying medical condition (CDC:3), assess and treat any underlying condition as appropriate, or refer. Provide DMPA based on findings

**INITIATING METHOD** (see Figure 27.1, page 128)
**A pelvic exam is NOT necessary prior to the initiation of this method** *[Stewart-2001]*
***Cycling women:***
- Preferred start time is during first 7 days from the start of menses
- Alternative: inject anytime in the cycle if not pregnant, back-up x 7 days (see 27.1)

***Postpartum women:*** May give injection prior to hospital discharge. Special considerations:
- After severe obstetrical blood loss, delay injection until lochia stops
- If woman has history or high risk for severe postpartum depression, observe carefully and delay injection at least 4-6 weeks
- Breast-feeding women: May either start DMPA immediately or wait 4-6 week.

***Women who have spontaneous or therapeutic abortion:*** May initiate immediately.
***Women switching methods:***
- May start anytime patient is known not to be pregnant
- Hormonal method: if she has been using her current method consistently and correctly, may initiate immediately
- If switching from non-hormonal method, offer same options as cycling women

**INSTRUCTIONS FOR PATIENT:** ***Some women may be able to give themselves Depo-Provera injections***
- **Do NOT massage area where shot was given for a few hours** (massaging area may reduce duration of action and thereby effectiveness)
- Expect irregular bleeding/spotting in beginning. Usually decreases over time. Return at any time spotting or bleeding is bothersome. Rx may make bleeding pattern more tolerable
- It is not harmful or dangerous if you do not have periods while you use DMPA

**WEIGHT GAIN: A TEACHABLE MOMENT**

When you see a patient who is very heavy or has gained enough weight to disturb her, you have a teachable moment. BE PREPARED FOR THAT TEACHABLE MOMENT.

***Simple messages to share:***

1. **Eat less (small, frequent meals helps some to lose weight); eat balanced diet with lots of fruits and vegetables and minimal saturated fats, chips, cookies, pasta and other carbohydrates**
2. **Exercise more...and every day**
3. **Find patterns of eating and exercising that you enjoy! You won't do them for long unless you enjoy the process.**
4. **Call Overeaters Anonymous (OA) - www.overeatersanonymous.org**
5. **Drink 8-10 glasses of water daily**

- Be sure to take in 1000 mg (women over age 25) to 1200 mg (adolescent women) of calcium every day to build your bones. Take calcium tablets like calcium carbonate or TUMS daily if your diet does not include enough calcium. Calcium is best absorbed when 500 mg is taken late in the day with a glass of orange juice. Get weight bearing and muscle-strengthening exercise at least 3 times a week (preferably 20 minutes daily)
- Return in 11-13 weeks for your next injection. Use abstinence, condoms, and EC, if necessary, if you are late coming for your re-injection (more than 13 weeks)
- Pregnancy is rare; return if you develop pregnancy symptoms other than amenorrhea
- Serious complications with DMPA are rare, but return if you develop severe headaches; heavy bleeding; depression or problems at the shot site (pus, pain, allergic reaction)

## FOLLOW-UP

- Are you experiencing spotting or irregular bleeding? Have you missed periods or had very light periods? Are you concerned about your pattern of bleeding?
- Did you have pain at the injection site after previous injection?
- Have you felt depressed or had major mood changes?
- Have you gained 5 pounds or more? (See WEIGHT GAIN, A TEACHABLE MOMENT, p. 125) Be sure to weigh patients at each visit. This means at **each and every visit**
- Consider measuring height and calculating a BMI
- Do you have any increase in your headaches?
- Have you had the feeling that you may be pregnant?
- Did you have any problems returning on time for this injection?
- Do you plan to have children? OR Do you plan to have more children?
- **What are you doing to protect yourself from STIs? When appropriate encourage condom use**

### STRUCTURED COUNSELING FOR DEPO-PROVERA PATIENTS WORKS!

- Discontinuation rates for DMPA users at 1 year are high in the absence of structured counseling: 70% in a New York study of low-income women *[Polaneczky-1996]*; 43.4% in a rural Mexican study *[Canto-DeCetina-2001]*
- Importance of focused, structured, repeated counseling at initiation and follow-up visits can't be overstated. See STRUCTURED COUNSELING p. 13
- Structured counseling may include repetition, having patient repeat back instructions, showing videotapes, providing videotapes, audiotapes and written instructions and asking focused questions such as "What has happened to your pattern of bleeding?", "Have your periods become extremely light?", OR "Does your pattern of bleeding bother you?" rather than unfocused questions like "Are you having any problems?"
- **Structured counseling in Mexico lowered DMPA discontinuation associated with three bleeding problems: amenorrhea, irregular bleeding and heavy bleeding, from 32% to 8%. Discontinuation from amenorrhea fell from 17 to 3%; from SPT or BTB from 10 to 3%; and from heavy bleeding from 5 to 2%** *[Canto-DeCetina-2001]*
- Weight should be taken at each visit and weight control discussed carefully if there has been weight gain (see progressive weight gain p. 129 and WEIGHT GAIN: A TEACHABLE MOMENT p. 125)

## PROBLEM MANAGEMENT

***Allergic reaction or vasovagal reaction:*** In acute setting, provide support as needed. Benadryl may reduce pruritus and swelling. Oxygen and other resuscitation may be needed for severe reactions (extremely rare). Most allergic manifestations subside in 1 week or so. Refer if symptoms severe or do not improve appropriately. Avoid future injections and help her choose a different method

***Vaginal dryness (dyspareunia) or atrophic vaginitis:*** May be due to hypoestrogenism. Consider measuring $E_2$ levels and giving physiologic replacement dose of estrogen, if needed. May give estrogen as vaginal cream, ring, tablets or systemic estrogen (tablets or patch) supplementation. Dyspareunia may be relieved with water soluble or silicone lubricants

***Pain or infection at injection site:*** Offer anti-inflammatory medications. Rule out infection or needle damage to nerve, etc. Provide appropriate antibiotics if cellulitis present

***Patient returns early (<11 weeks) wanting reinjection (eg b/c of travel):*** May give DMPA

***Patient returns late (>13 weeks) for reinjection:*** See Figure 27.1 on page 135

- WHO guidance: repeat injection of DMPA can be given up to 4 weeks late without requiring additional contraceptive protection.
- This does not mean that the regular DMPA interval can be extended by 4 weeks

***Switching to another method (eg OCs, IUD, etc) from DMPA:*** Initiate new method at any time convenient for patient. Preferred time would be near end of effectiveness of last DMPA injection unless switching to OCs, patch or vaginal rings to control menstrual disorders on DMPA. **Do NOT wait until next menses to start pills**. She may have amenorrhea for a number of months after DMPA

***Transitioning perimenopausal women:*** See Figure 27.2 on page 129

***Weight gain:*** Advise to watch caloric intake and to increase exercise. Refer to OA, Overeaters Anonymous. **Be ready to discontinue method if weight gain is excessive or unacceptable** (See teachable moment p. 125)

***Heavy bleeding:***

- Rule out pregnancy, cervical infection or neoplasia and other causes
- Rule out anemia - recommend iron rich foods and/or supplements
- May treat with NSAIDs or low dose estrogen supplements:
  - Ibuprofen 800 mg orally every 8 hours for 3 days
  - Mefenamic acid: 500 mg once, then 250 mg every 6 hours for 2-3 days
  - Conjugated equine estrogen (2.5, 1.25 or 0.625 mg) orally once a day up to four times per day for 4-6 days OR ethinyl estradiol x 21 days (expensive)
  - COCs for 1-2 months (in addition to DMPA use)

***Irregular bleeding and spotting:***

- **Reassure that cumulative blood loss is usually less not more**
- Rule out infection or cervical lesions as source
- Reassure that irregular spotting and bleeding is to be expected in first several months
- May use same therapies as outlined in heavy bleeding section above

***Amenorrhea:***

- Reassure her that this is not a medical problem. Do pregnancy test if she has other Sx.
- Switch method if patient desires regular menses (consider patch, ring, COCs). Even if she stops DMPA, menses may not return for months

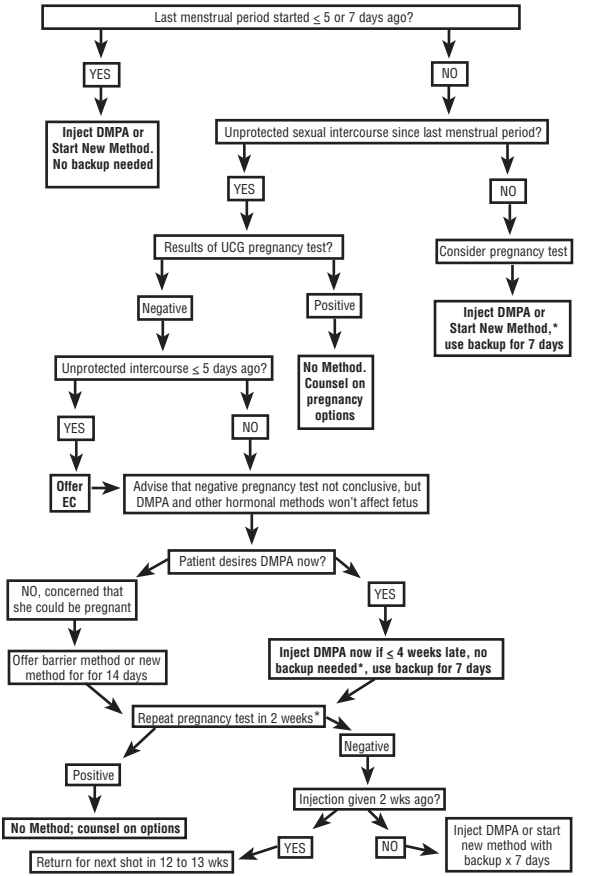
***Depression:***

- Evaluate suicide potential and refer immediately, if indicated
- Explain that DMPA usually does not worsen depression. Start antidepressant therapy, if needed. Discontinue DMPA if you or your patient has any misgivings about continuing its use

## FERTILITY AFTER DISCONTINUATION OF METHOD

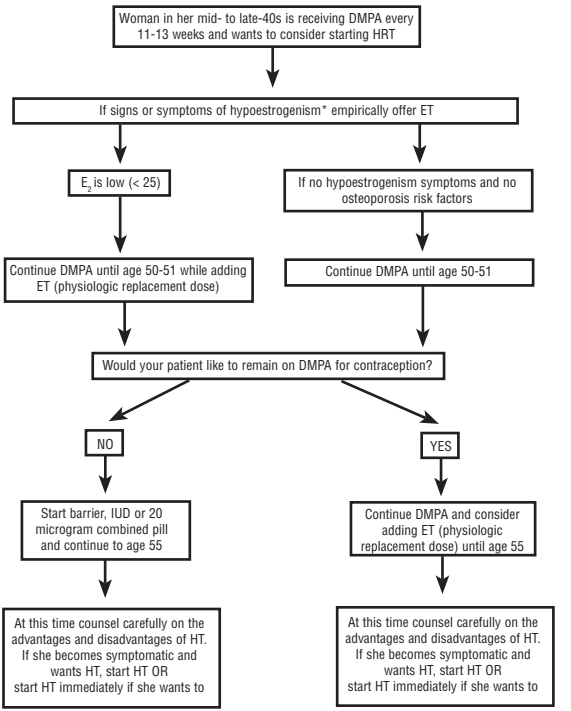
- **Because anovulation may last for more than 1 year, women who know they will want to become pregnant within one year of cessation of use would be wise to consider another option, especially women over 35 years of age**
- Fertility returns afer 3 months; however, the conception rates overall are lower than women discontinuing other contraceptive methods. After last shot, 50% of women are pregnant after 6-7 months (compared to 4 months with other methods). (Delay not increased with increased duration of use). More than 90% of women become pregnant within 2 years
- Women who do not want to await spontaneous return of ovulation will require gonadotrophin therapy to induce ovulation. Gonadotropins will not overcome effect of DMPA on cervical mucus

**Figure 27.1 Initial Injection or Late Reinjection (more than 4 weeks since scheduled return visit at 13 weeks) of DMPA or Switching From DMPA to COCs or Another Hormonal Method***




*Steiner MJ, Kwok C, Starback J et al. Contraception 2008 77 (2008) 410-414.

**Figure 27.2 Making Transition from DMPA to Menopause, With or Without Hormone Replacement Therapy (HRT, EPT, or HT)**




* DMPA can suppress gonadotropins, so measuring FSH or LH may not be informative of menopausal state. DMPA use decreases endogenous estrogen levels. Long-term DMPA users in their 40s may benefit from estrogen supplementation *[Kaunitz, 1998]*. Some researchers recommend that, at age 50, 2 FSH measurements be done at injection visit to assess menopausal status. If 2 consecutive levels are $\geq$ 35-40 m IU/ml, this is suggestive of menopause *[Juliato-2007]*

## IMPLANTS: IMPLANON - THE SINGLE ETONOGESTREL IMPLANT

Approved 2006

**DESCRIPTION:** Single implant is 4-cm long and 2 mm in diameter (5 mm longer than one Norplant implant), with a membrane of ethylene vinyl acetate (EVA) copolymer and with a core of 68 mg of etonogestrel in EVA (the new name for 3-ketodesogestrel). Initially, progestin is released at rate of 60 µg per day decreasing to 25-30 mcg/day by end of year 3. Implanon is effective for at least 3 years. Implant is placed under the skin of upper arm with a 16 gauge disposable, preloaded inserter

**EFFECTIVENESS:** No pregnancies in earliest studies. Some postmarketing pregnancies. Overall, 82% of women continue to use Implanon for 2 or more years. Women > 30% above ideal body weight excluded from studies. However, serum concentration of ENG remains high enough to suppress ovulation (0.3 ng/ml) even in heavier users

### HOW IMPLANON WORKS:

- Within 24 hours of insertion thick cervical mucus prevents normal sperm transport
- Inhibition of ovulation. No ovulation in first 2 years and only 2 women had 4 ovulatory events in third year of Implanon use. However, they did not get pregnant
- Atrophic endometrium

**COST:** $595.28 - Private Sector/ $262.00 - Public Sector

### ADVANTAGES

***Menstrual:*** Decreased menstrual and ovulatory cramping or pain; overall, less bleeding than with Norplant and more amenorrhea (15% at one year). Less anemia. Dysmenorrhea decreases by 48% *[Affandi-1998]*

***Sexual/psychological:***

- Sexual intercourse may be more pleasurable because fear of pregnancy is reduced
- Usage not linked to sexual intercourse—allows spontaneity

***Cancers/tumors and masses:*** None

***Other:***

- High continuation rate in clinical trials. Cyclic headaches may improve
- Single implant is easier and faster to insert and remove than multiple implants. Removal is usually accomplished with only a #11 scalpel and gentle finger pressure with < 1.0 cc ml of local anesthetic (use tuberculin syringe)
- Asymptomatic (usually ) follicular cysts are less common

### DISADVANTAGES

***Menstrual:***

- Unpredictable/irregular menstrual bleeding frequent and may persist but usually is light and well tolerated
- Amenorrhea and oligomenorrhea common

***Sexual/psychological:***

- Irregular bleeding may inhibit sexual intercourse
- Insertion and removal require procedures, for which special training is needed

***Cancers/tumors and masses:*** None

***Other:***

- No STI protection
- Hormonal side effects: headache is most common
- May develop acne (or acne may improve)

- Ovarian cysts; usually resolve without treatment ←
- Dependent on clinician to remove ←

**COMPLICATIONS:**
- Removal difficulties much less frequent than with Norplant
- Rarely, sonographic or MRI localization is required
- Rare infections ←

**CANDIDATES FOR USE:**
- Implanon is particularly good for women with contraindications to or side effects from estrogen:
  - Women with personal history of thrombosis
  - Recently postpartum women
  - Women who are exclusively breast-feeding as there are no effects on breast milk or ← breast-feeding infants associated with Implanon use *[Reinprayoon-2000, Taneepanichskul-2005]*
  - Smokers over age 35
  - Women who had or fear chloasma, worsening migraine headaches, hypertriglyceridemia or other estrogen-related side effects
  - Women with hypertension, coronary artery disease or cerebrovascular disease

**PRESCRIBING PRECAUTIONS, MEDICAL ELIGIBILITY CHECKLIST, INITIATING METHOD:**

Same precautions as for progestin-only pills

**INITIATING METHOD:**
- If inserted within 7 days of LMP, no backup needed. Can be inserted any time of cycle if reasonably certain not pregnant. If later than 7 days from LMP, use backup x 7 days
- If has been on DMPA, insert at time next injection due. No backup needed

**INSTRUCTIONS FOR PATIENT**: Irregular bleeding is to be expected and persists while rod is in place. If your pattern of bleeding is unacceptable, come back because there are several treatments that may make your bleeding pattern more acceptable (Periodic COC, patch, ring use). Amenorrhea more likely than with Norplant, but less likely than with DMPA

**FOLLOW-UP:** Routine GYN follow-up

**PROBLEM MANAGEMENT:**

***Amenorrhea:*** Quite common. Pregnancy test if symptoms of pregnancy

***Spotting/breakthrough bleeding:*** to be expected; not harmful. If bothersome may provide several cycles of low-dose pills, patch or rings or NSAIDs

***Arm Pain after insertion***
- Rule out nerve damage or infection
- If due to bruising, advise her to make sure bandage is not too tight
- Apply ice packs for 24 hours
- Take acetaminophen or NSAID

***Infection in insertion area***
- *No abscess:* cellutlitis only. Do not remove, Clean infected area with antiseptic. Oral antibiotics for 7 days. (Recheck in 24-48 hours to make sure improving and at end of therapy)
- *Abscess:* Preload with antibiotics; prepare infected area with antiseptic, make incision, drain pus, and remove implant. Continue antibiotic therapy and wound care

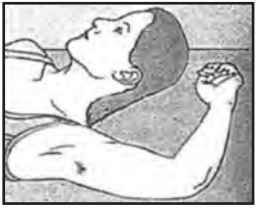
***Difficult to locate rod:*** may be found by ultrasound or MRI. This requires experienced sonographer using tranducer of 10 MHz or greater. Rarely, there may be a failure of provider to insert the rod (implant left in inserter) ←

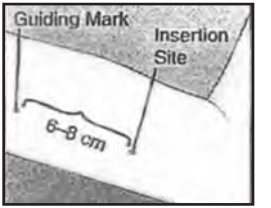
**FERTILITY AFTER DISCONTINUATION OF USE**: Return to baseline fertility is rapid and complete; 94% ovulate within 3-6 weeks of removal

## IMPLANON INSERTION

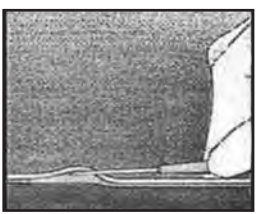
- Implanon can be prescribed only by clinicians who have personally attended a company sponsored training session (Organon - for training, call 1-877-Implanon or visit www.implanon-usa.com)
- For full review, see package insert

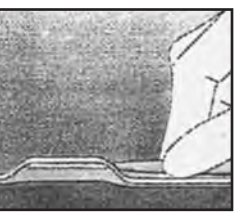
1. Patient should lie on her back with her non-dominant arm flexed at the elbow and externally rotated
2. Insert 6-8 cm above the elbow at the inner side of upper arm over the groove between the biceps and triceps muscles





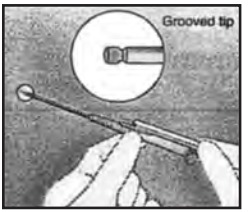

3. Mark planned track with a pen or marker
4. Clean site with antiseptic
5. Anesthetize area with 1-2 cc lidocaine (1%) subdermally along planned track of insertion
6. Carefully remove Implanon applicator from package. While shield is still on needle, look for Implanon rod (white) on tip of applicator. If not seen, carefully tap the top of needle (with shield) against hard surface to bring implant to needle tip
7. Following visual confirmation, lower the Implanon rod back into the needle by tapping it back into the needle tip, then remove the needle shield while holding the applicator upright
8. Note that the Implanon can fall out of the needle. Therefore, keep the applicator upright
9. Apply counter-traction to the skin around the proposed insertion site, and insert the needle at an angle - not greater than 20°, with the beveled side of the needle facing up
10. Keeping the needle in the subdermal tissue, lower the applicator to a horizontal position and insert just under the skin. Tenting of the skin helps to **keep it superficial and parallel to the surface of the skin**





11. When inserted to its fill length, press the obturator support to break the seal and turn the obturator 90° in either direction

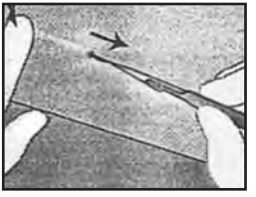
12. Hold the obturator fixed – and fully retract the cannula
13. Confirm that Implanon has been inserted by a) inspecting the needle tip for the absence of Implanon and the visualization of the grooved obturator tip and b) palpating the arm for the Implanon – have patient palpate too.

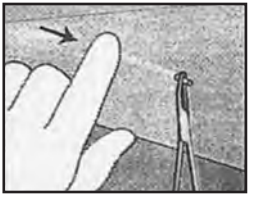



14. Apply adhesive bandage and pressure bandage. Patient may remove pressure bandage in 24 hours and adhesive bandage in 3-5 days
15. Complete the user card and give to patient to keep and complete patient chart label and affix to medical record

**IMPLANON REMOVAL:**

1. Palpate arm for Implanon
2. If Implanon not palpable – obtain imaging study. Implanon can be imaged with ultrasound that uses a high frequency linear array transducer – at least 10 MHz, or with MRI. If these imaging methods fail, call 1-877-Implanon for further instructions
3. The prescribing information for Implanon states that Implanon should only be removed by clinicians trained in the Implanon removal technique
4. Palpate the rod, apply antiseptic and anesthetize where the incision will be made. Apply the anesthetic under the tip of the implant closest to the elbow, and make a 2-3 mm incision in the longitudinal direction
5. Apply pressure on the proximal (closest to the head) tip of the implant gently pushing out of the incision. If the implant is encapsulated by fibrous tissue, make an incision in the fibrous sheath and then remove the Implanon with forceps





6. A new Implanon may be inserted in the same incision if desired

The incision can be closed with an adhesive bandage, followed by a pressure bandage. Patient may remove pressure bandage in 24 hours and adhesive bandage in 3-5 days

# CHAPTER 26

# Female Sterilization: Tubal Ligation or Occlusion

**www.engenderedhealth.org, www.plannedparenthood.org or www.essure.com**

**DESCRIPTION:** Surgery to interrupt the patency of fallopian tubes. In 2002 in the USA, 27% of married women reported having had tubal sterilization while 9% of their husbands had a vasectomy *[Mosher-2004]*. Many single women have sterilization operations. Approximately half of sterilizations in the USA are done in the postpartum period within 48 hours of delivery *[Peterson-1998]*.

**EFFECTIVENESS:** Failure rates vary depending on sterilization method and patient's age.

**Table 28.1 Cumulative 10-year failure rates for some methods of voluntary female sterilization methods***

| *Method* | *Failure rate (highest rate)* |
|---|---|
| Postpartum partial salpingectomy | 0.8%* |
| Silastic bands over loop of tube | 1.8%* |
| Interval partial salpingectomy | 2.0%* |
| Bipolar cautery | 2.5%* |
| Spring clip application | 3.7%* |
| Filshie clip (7 years) | 0.9%+ |

For each sterilization method, at least 50% more failures were ascertained AFTER 2 YEARS as had been identified in the 2 years immediately following the sterilization procedure

** U.S. Collaborative Review of Sterilization. The risk of pregnancy after tubal sterilization. Am J Obstet Gynecol 1996;174:1161-70.*

*+ Filshie clip (0.9% failure rate - 7 years) [Chi-Chen Contraception 1987;35:171-8]*

- Younger women had higher failure rates
- All methods require proper application to maximize effectiveness
- Teaching institution rates(above study) may differ from private settings

**Hysteroscopic tubal occlusion:** 99.74% effective at 5 years (if post-op verified occlusion by hysterosalpingogram) ←

**HOW FEMALE STERILIZATION WORKS**: Interruption of patency of the fallopian tubes preferably in isthmic region thereby preventing fertilization

## LAPAROSCOPIC STERILIZATION: TRANSABDOMINAL

***Bipolar cautery:***

- Apply to area along fallopian tube with no vessels ascending through broad ligament, where the diameter of tube is similar on either side of selected area (at least 2 cm from uterotubal junction). Thoroughly cauterize tissue using bipolar cutting current of 25 Watts passing through jaws of instrument. Bipolar cautery has the highest risk of subsequent fistulization and ectopic pregnancy.

***Silastic band:*** (Fallope Ring, Yoon Band)

- Apply over knuckle of tube at least 3 cm from utero-tubal junction. Loop of banded tube should clearly contain two complete diameters of tube

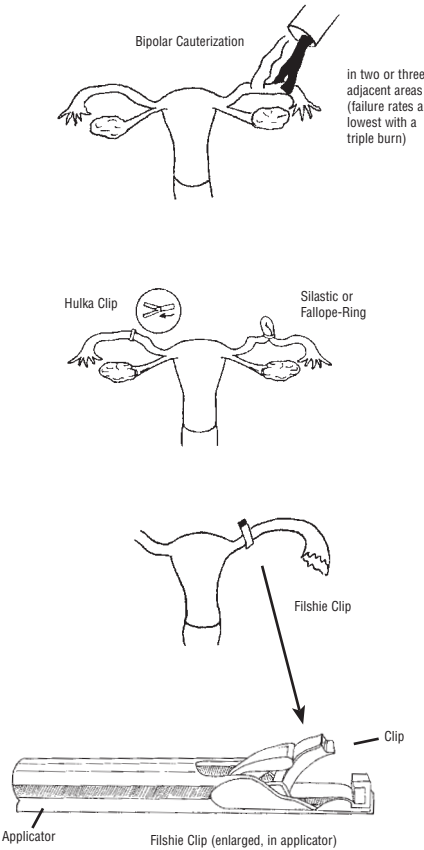
***Hulka-Clemens clip (spring clip):***

- Spring-loaded clip. Apply to isthmic portion of tube. 1-2 cm distal to cornu at an angle of 90% relative to long axis of tube. Highest failure rate

***Filshie clip:***

- Hinged titanium clip with cured silicone rubber lining. Apply to isthmic portion of tube, 1 to 2 cm from cornu. Should see hook end of clip through filmy mesosalpinx. May apply postpartum with special applicator (0.9% failure vs. 0.4% failure for interval application)

**Figure 28.1 Laparoscopic Technique Diagrams**



## POSTPARTUM OR INTERVAL MINI-LAPAROTOMY METHODS

***Modified Pomeroy:***

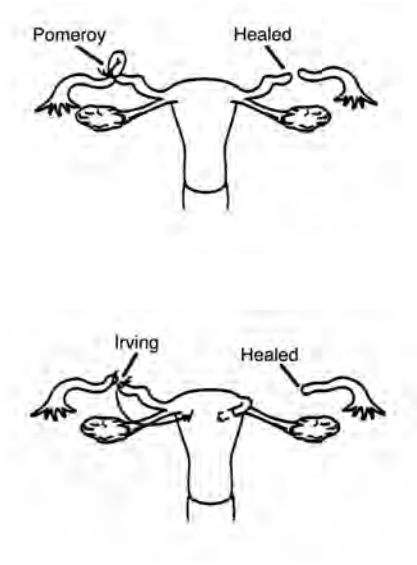
- Ligation at the base of a loop of isthmic portion of tube with plain absorbable catgut suture (2 separate ties) followed by excision of the knuckle of tube. Segment is histologically confirmed to contain tubal ostia.

***Modified Parkland:***

- Excision of segment of isthmic portion of tube after separate ligation of cut ends, no "knukle formed"

***Irving, Uchida and Fimbriectomy are rarely performed*** ←

**Figure 28.2 Postpartum or Mini-Laparotomy Techniques**



## ADVANTAGES

***Menstrual:*** None

***Sexual/psychological:*** Enhanced enjoyment of sex by reducing worry of pregnancy

***Cancers, tumors, and masses:***

- Decreased risk of ovarian cancer. Women with BRCA 1 mutations who have undergone a tubal ligation have a 60% lower risk of developing invasive ovarian cancer. *[Narod-Lancet 357 (9267): 1467-70, 2001].* Overall 40% reduction in risk of ovarian cancer

***Other:***

- Permanent and highly effective

## DISADVANTAGES

***Menstrual:***

- Data from 9514 women who underwent tubal sterilization by 6 techniques and followed for up to 5 years suggest no "post-tubal ligation syndrome" and no increases in the amount or duration of menstrual bleeding or menstrual pain. *[Peterson, 2000]*

***Sexual/psychological:***

- Regret may occur especially with young patients; counsel well and offer reversible methods if any hesitancy (see Fig. 28.5, p. 140)

***Cancers, tumors, and masses:*** None

***Other:***

- Requires outpatient surgery (usually with general anesthesia); Expensive in short term
- If failure occurs, higher risk of ectopic pregnancy (30%)
- Not readily reversible
- Does not prevent spread of HIV and STIs

## COMPLICATIONS *[Peterson, 1997]*

| | ***Minilaparotomy*** | ***Laparoscopy*** |
|---|---|---|
| ***Minor*** | 11.6% | 6.0% |
| ***Major*** | 1.5% | 0.9% |

- Minor complications include infection, wound separation
- Major complications include conversion to laparotomy, hemorrhage, viscus injury especially with cautery, anesthetic complications
- Major vessel injury risk with laparoscopy 3-9/10,000 procedures
- Mortality: 1-2/100,000 procedures (leading cause is general anesthesia)

## LONG-TERM RISKS

- Statistically higher risk for subsequent hysterectomy, but only in women who had gynecologic complaints prior to sterilization
- Regret (0.9% - 26.0%) Risk factors include: age under 30, low parity, sterilization at time of cearean delivery, change in marital status, poverty, minority status, misinformation about permanence or risks, hurried decision. If sterilized < 30 years old, 40% requested information on reversal, 20% expressed regret but only 1% had a reversal done *[Schmidt-2000]*. **This issue requires careful counseling**

## CANDIDATES FOR USE

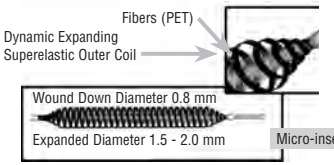
- Woman who is certain she wants no more children
- Woman over age 21 (only required for Medicaid reimbursement, not for medical requirements or for California state funding)
- Woman for whom surgery is considered safe

***Adolescents:*** Not a preferred method, generally higher regret and higher failure rates

## ESSURE: HYSTEROSCOPIC STERILIZATION VIA POLYESTER FIBERS

***www.essure.com*** Essure is a new approach to transcervical sterilization that causes tubal blockage by encouraging local tissue growth with polyesther (PET) fibers *[Valle Fertil Steril 2001]*. An attached outer coiled spring is released that molds to the shape of the interstitial (uterine) portion of each fallopian tube. The device costs $950 *[Ballagh, 2003]*, but it is covered by insurance plans that cover laparoscopic tubal ligation (even Medicaid). It takes 3 months after procedure to occlude tubes. An hysterosaplingogram (HSG) is needed 3 months after surgery to document success

**Figure 28.3 Essure System Overview: Micro-Insert Design**




*Source:* Association of Reproductive Health Professionals. Trancervical methods in the U.S. pipeline. *Clinical Proceedings* 2002; May:9.

**ADVANTAGES: "The alternative to incision"**

- Provides tubal sterilization in physician's or ambulatory surgery office (average operating time: 13 to 35 minutes)
- No change in a woman's menstrual cycles
- No failures among 453 women relying on Essure for one year following confirmation of tubal blockage at 3 months by hysteroscopy; 99.8% effective. 99.7% effective at 5 years
- There is no need for conscious sedation or general anesthesia (nonsteriodal premedication is strongly recommended to prevent tubal spasm)
- In clinical trial, (Australia, Europe, and the U.S.) 92% of women returned to work in one day, most resumed normal activities the same day as the procedure
- May be preferred for obese women, women with abdominal adhesions, or women with risk factors for anesthesia

**DISADVANTAGES: Requires specialized training and equipment**

- **Hysterosaplingogram must be done at 3 months to confirm blockage. Until that time, couple must use another contraceptive.**
- Procedure designed for interval sterilization. It is not to be used at Cesarean delivery or immediately postpartum *[Bullagh, 2003]*
- Luteal pregnancies occured in 4 of 466 women in spite of negative urine pregnancy tests on the day of the procedure
- It may not be possible to visualize both tubal ostia (this occurs about 2% of the time)
- May require more than one operative procedure
- In only 446 of 518 women (86.1%) could devices be introduced into both tubes at the time of the first procedure due to difficulty locating tubes, tubal spasm or tube already not patent
- Expulsion of one or both devices (14 of 466 successful procedures or 3.0%)
- Perforation of the uterus occured during 1% of procedures
- This form of sterilization cannot be reversed

## PRESTERILIZATION COUNSELING CHECKLIST*

- Discuss alternative reversible methods and quote their effectiveness. (IUDs and implants are more effective than some forms of tubal sterilization)
- Discuss vasectomy as an alternative
- Insure patient commitment to having no future children, even if something happened to her current family
- Describe details of surgery (informed consent later) and possible intraoperative and long-term complications (risk for ectopic pregnancy)
- Stress that procedure must be considered irreversible and that about 10% of women regret their decision and answer all of her questions
- Discuss that ~ 2% of laparoscopic and transcervical procedures cannot be completed on first attempt. Review the "what if" intended procedure cannot be completed
- Obtain informed consent using locally approved consent forms - No requirement that spouse must be involved

**Adapted from ACOG Technical Bulletin, April 1996.*

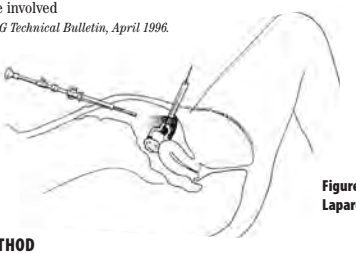


**Figure 28.4**
**Laparoscopy**

## INITIATING METHOD

- Obtain informed consent. Preferable to involve partner in process, but not necessary
- Any time in cycle with certainty of no conception, otherwise follicular timing preferred. Not true for Essure. With Essure, you want to time when lining will be very thin
- The routine provision of antibiotics is generally NOT recommended *[see ACOG Practice Bulletin No. 23, January 2001]*

## FOLLOW-UP

- For women having interval occlusion procedure, follow up in two weeks for post-op wound check is typical, but not required. Routine annual gynecology exams
- 3-month follow up visit for Essure (see p. 138)

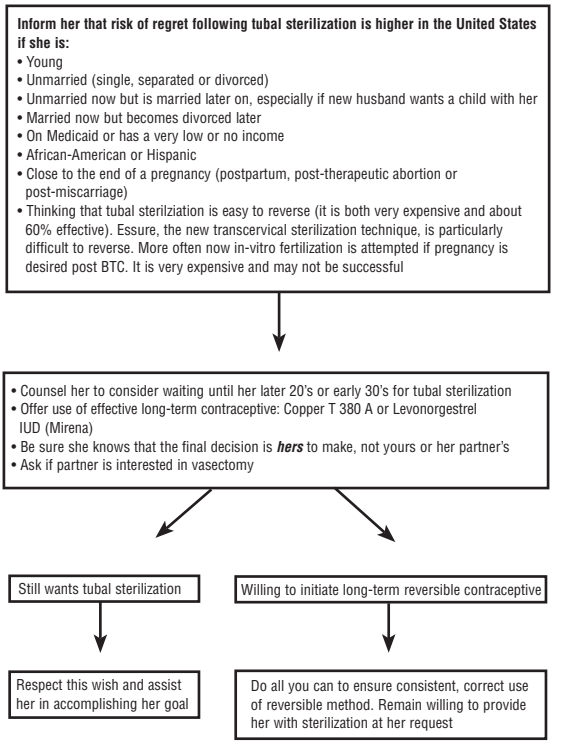
## MANAGEMENT OF PROBLEMS

- Anesthesia complications, wound infections, intraperitoneal adhesion formation, hydrosalpinx – managed with standard approaches
- Although some women report irregular menses or dysmenorrhea after tubal sterilization, several studies have demonstrated that a syndrome of irregular menses or dysmenorrhea following tubal sterilization does NOT exist *[Peterson-2000]*. These problems are **not** apt to develop at any higher rates in sterilized women. They are most likely age-related and inevitable

## FERTILITY AFTER TUBAL STERILIZATION

- Women must desire to be permanently sterile because reversal is costly and results are unpredictable. In vitro fertilization may be possible, but many cannot afford this procedure and it is not always successful

## Figure 28.5 Sterilization Requested by Young Woman



# CHAPTER 27

## Male Sterilization: Vasectomy

**www.engenderedhealth.org or www.plannedparenthood.org**

**DESCRIPTION:** Permanent male contraception. Outpatient surgical procedure. No-scalpel technique punctures scrotum, delivers vas; ligates or cauterizes vas. Nearly 1 in 5 white U.S. men married to women of childbearing age has had a vasectomy. *[Amba-1997]*

**EFFECTIVENESS** (See Table 13.2, p. 40)
***Perfect use failure rate in first year:*** 0.10%
***Typical use failure rate in first year:*** 0.15%
*[Trussell J, IN Contraceptive Technology, 2004]*
Recent analysis of the 540 women in the CREST study who were protected by vasectomy found a cumulative failure rate of 9.4 per 1000 procedures at one year (0.9%) and 11.3 at years 2, 3 and 5. *[Jamieson, Costello, Trussell et al-2004]*

Although vasectomy is safer and potentially more effective than tubal sterilization, as of mid-2000, there are only 4 nations in the world where vasectomies exceed tubal sterilizations: Great Britain, the Netherlands, New Zealand and Bhutan.

**HOW VASECTOMY WORKS:** Interrupts vas deferens preventing passage of sperm into seminal fluid and female reproductive tract

Vas deferens isolated following incision with scapel

### ADVANTAGES

***Sexual/psychological:***
- Sexual intercourse may be more enjoyable because fear of pregnancy decreased
- Permits man opportunity to take on an important contraceptive role
- No interference during sexual intercourse and no contraceptive burden for female

***Cancers, tumors, and masses:*** None

***Other:***
- Simpler, safer and more effective than female sterilization
- More cost-effective than female sterilization and more convenient
- Shares contraception responsibility with partner
- No supplies or further clinic visits needed after sperm count has been documented to be zero
- Only local anesthesia required

### DISADVANTAGES

***Sexual/ psychological:***
- Some men resist vasectomy fearing that it will interfere with sexual function (it doesn't) or because they feel contraception is solely the woman's responsibility (it isn't)
- Regret at a later time possible (1% of men request a reversal)
- Will need back-up method until there are no motile sperm. Female partner may still need contraception if she has other partner(s) or if STI protection needed

***Cancers, tumors, and masses:*** None

***Other:***
- Does not reduce risk for STIs; will still need to use condom if at risk
- Short-term post-operative discomfort, bruising, and swelling

### COMPLICATIONS

- Surgically related complaints such as hematoma, bruising, wound infection, or adverse reaction to local anesthesia
- Severe chronic pain (2%) *[Choe, Kirkema - 1996].* Usually limited to less than 1 year
- Later regret possible

**CANDIDATES FOR USE:** Men who desire a permanent method

## INITIATING METHOD

- Take preoperative history; make general health assessment
- Ask if history of genital infections or anomalies ←
- Obtain informed consent. In general, try to involve partner
- Carefully counsel, especially about permanence of method
- Advise patient to bathe genital area and upper thighs prior to surgery; wear clean, loose-fitting clothes to facility; no food for 2 hours before procedure

## PRESCRIBING PRECAUTIONS

- Current infection of penis, prostate, or scrotum
- Fear of needles or scalpels (scalpels not required if no-scalpel vasectomy)

## INSTRUCTIONS FOR PATIENT

- Plan to rest for 48 hours and wear scrotal support
- Apply ice pack to incision site to decrease swelling, pain and bruising. Small packages of frozen peas conform well around the scrotum
- Keep area dry for two days – wear snug underwear and pants to provide support where needed
- If any symptoms or signs of infection develop, seek help immediately.
- Return as directed for sperm counts. Results from a new study suggest that azospermia is more likely after 12 weeks (60% azospermia) than after 20 ejaculations (28% azospermic) and that neither endpoint is ideal *[Barone-2003]*. Use other forms of contraception until two consecutive sperm samples show no motile sperm

**FOLLOW-UP:** ***To avoid failure due to LATE recanalization, repeating semen analysis every few years makes sense***

- Have you had your semen tested? If yes, were motile sperm absent?

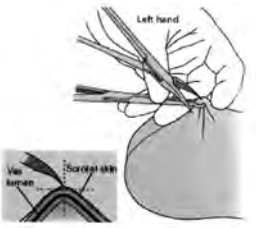
## PROBLEM MANAGEMENT

***Wound infection:*** Treat with antibiotics. Drain and treat any abscesses
***Hematoma:*** Apply warm moist packs to scrotum. Provide scrotal support
***Granuloma:*** Observe; usually it will resolve itself. Occasionally requires surgery
***Pain at site:*** If no infection, provide scrotal support and analgesics
***Excessive swelling:*** If large and painful, may require surgery. Provide scrotal support if hematoma
***Chronic persistent pain considered to be severe:*** *[2% - Choe, Kirkema - 1996]*. IPPF Handbook states that this pain can often be relieved by vasovasectomy or decompression of the distended vas deferens releasing the sperm into the scrotal cavity *[Evans, Huezo IPPF Handbook - 1997]*

## FERTILITY AFTER VASECTOMY

- Man must accept that vasectomy is irreversible and permanent
- Microsurgical techniques of reversal now result in return of sperm to ejaculate in over 90% of men, but in pregnancy rates of only 50% or above. Reversibility rates decrease as time passed since procedure increases
- Important factors for reversal are
  - skill of microsurgeon
  - length of time since vasectomy
  - presence of antisperm antibodies (man)
  - partner's fertility
  - manner in which vasectomy was performed (amount of vas removed or cauterized)

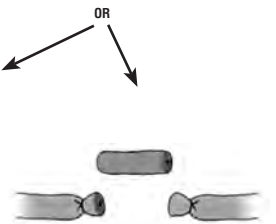
**Figure 29.1 Vasectomy - No-Scalpel Techniques**




A) Piercing the skin with the medial blade of the dissecting forceps

B) Grasping a partial thickness of the elevated vas at the crest of the loop, with only the ringed clamp attached

Cautery with a blunt wire inserted into the hemitransected vas (done in each direction)




Ligation and section

Cornell No-Scalpel Vasectomy Center. No-Scalpel Vasectomy. http://www.vasectomy.com/no-scalpel-vasectomy-diagram.html.2/6/02.

# CHAPTER 28

## Ordering and Stocking Devices: Implanon, Mirena, ParaGard

**www.implanon-usa.com, www.mirena-support.com, www.paragard.com**

**ORDERING AND STOCKING DEVICES:** Telephone numbers below are for ordering devices, speaking with customer service, reporting adverse events.

### IMPLANON

- Call 1-877-Implanon, www.implanon-usa.com
- Implanon dispensed by two pharmacies: CuraScript and CVS Caremark ←
- To set up account, need state license number and DEA number
- Pharmacy verifies that health care provider (HCP) has attended a company sponsored Implanon training program
- Implanon is usually a "medical benefit"; sometimes a pharmacy benefit
- If Implanon contaminated prior to insertion or touching the patient – call 1-877-Implanon (option 3) and save the product to ship back to manufacturer for free replacement
- HCPs may complete and fax a benefits search (determine if an individual's insurance covers Implanon) to pharmacy. Search completed within 48-72 hrs. ***Cost*** of implant alone (if no insurance): $595.28 ← Payment plans available. For information, call 1-877-Implanon and press option #6 ←

### MIRENA

- Call 1-866-647-3646, www.mirenasupport.com, www.mirena-us.com, www.archfoundation.com
- To set up an account, clinician needs license. Bayer verifies that the HCP is certified (i.e. trained by a medical specialist, or has attended a company sponsored training program). If not, a training kit will be included in the order ←
- Verify insurance coverage
- If no coverage, patients can pay by credit card with Mirena shipped to HCP.
- Low income patients can apply to the ARCH foundation (1-877-393-9071) or www.archfoundation.com for a subsidized Mirena
- If Mirena is contaminated upon insertion, or removed early for a medical reason, no general replacement policy exists. However, by calling the hotline or their Bayer sales consultant, they will consider each event on a case-by-case basis. ←
- ***Cost*** (of IUS if no insurance): $843.60 (single payment). Patient may pay by 4 ← installments: First payment is: $337.44 and then 3 payments at $168.72 each or 24 equal payments of $35.15. Call 1-866-638-8312 to take advantage of one of these plans. Mirena will be ordered by health care provider and shipped to the office within 2 to 3 business days.

### PARAGARD

- Call 1-877-727-2427, www.ParaGard.com
- To set up an account, a clinician needs a state license number
- Verify patient insurance coverage prior to insertion
- If no coverage, patients can pay by credit card / ParaGard shipped to HCP
- Replacement policy: If a clinician contaminates the IUD prior to touching the patient (e.g., drops on floor), call the hotline within 7 days AND save the product to ship back to them. They will send a replacement. If the woman has the ParaGard removed for a medical reason within 90 days (and reported within 30 days of removal) they will replace the product if the patient desires. If patient paid for IUD – she will be reimbursed. If she paid and is not ← satisfied with the IUD, she can get a full refund within the first 150 days
- ***Cost*** (of IUD if no insurance): $ 494.00. or 12 credit card payments of $41.17 ←

# CHAPTER 29

## HPV Vaccine

**www.cdc.gov, www.acog.org, www.gardasil.com, www.cervarix.com**

**HPV VACCINE:**

- Quadrivalent vaccine (Gardasil) protects against infection with HPV types 6, 11, 16, 18 which account for 70% of HPV-related cervical cancer and 90% of genital warts
- Vaccine prepared from highly purified virus like particles (VLPs) of the major capsid protein of the HPV
- IM injection to deltoid or thigh
- Designed to prevent the following conditions caused by HPV 6,11,16,18 (these conditions may still occur related to other HPV types): cervical dysplasia and cancer, vulvar or vaginal dysplasia and genital warts
- Now offered to males ages 9-26 also for prevention of warts
- 4 Phase 2 and 3 randomized, placebo controlled trials evaluated 20, 451 women ages 16-26. Median duration of follow-up was 4,3,2.4 and 2 years
- Vaccine was found to be highly effective in preventing acquisition of disease
- Vaccine is a preventive tool, not a substitution for cervical cancer screening. These recommendations remain unaffected by the vaccine's approval and use
- Administered in a series of 3 innoculations: initial injection, then 2 months and 4 months after that
- Approved for females ages 9-26: Federal Advisory Committee on Immunization Practices (ACIP) recommends administering to girls between ages 11 and 12; may be given from age 9
- Women with previous HPV infection or abnormal cytology can still be vaccinated and may benefit from protection from strains they may not have yet acquired. Benefits in these women may be more limited and women should be informed of this. Benefits may also decrease in women who have had $\geq 5$ lifetime sexual partners
- Vaccination is not treatment for genital warts
- Immunosuppression is not a contraindication to vaccination; efficacy may be affected
- Currently not recommended to vaccinate women > 26 y/o
- New HPV vaccine, Cervarix, recently approved for use in females aged 10-25. Protects against HPV types 16, 18

**CERVICAL CANCER SCREENING GUIDELINES UNCHANGED**

***SEE Prescribing Information for full information***

***Contraindication:*** hypersensitivity to vaccine components. If sensitivity occurs after first dose, do not administer subsequent doses

***Precaution:*** may not result in protection for all recipients

- Not intended to be given to pregnant women, pregnancy category B. Pregnancy registry: 1-800-986-8999
- Adverse events include pain, swelling, erythema, pruritis at injection site

# CHAPTER 30

# Sexually Transmissible Infections (STIs) 2006 CDC Guidelines for Treatment*

**Complete guidelines at www.cdc.gov/nchstp/od/nchstp.html**
**www.hab.hrsa.gov www.aidsinfo.nih.gov**

Since women and men seeking contraceptives are also at risk for STIs, we have included in this book information on the treatment of many of the most important STIs based on the latest abridged CDC recommendations (2006). Please refer to the full document for comprehensive information



## CLINICAL PREVENTION GUIDELINES

- The specific recommendations presented here are from that document
- Both partners should be tested for STIs, including HIV, before initiating sexual intercourse
- A new condom should be used for each act of insertive intercourse (oral, vaginal or anal)

***Prevention Methods***

- *Male Condoms*
  - Used consistently and correctly, latex condoms are effective in preventing the transmission of HIV infection and can reduce the risk for other STIs
  - Failure usually results from inconsistent or incorrect use, rather than condom breakage

- *Female Condoms*
  - Laboratory studies indicate that the Reality female condom is an effective mechanical barrier to viruses, including HIV
  - Used consistently and correctly, the female condom may substantially reduce risk for STIs including HIV

- *Condoms and Spermicides*
  - Condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against HIV and STDs
  - Use of condoms with N-9 is not recommended for HIV/STD prevention

- Vaginal spermicides containing N-9 are not effective in preventing cervical gonorrhea, chlamydia or HIV infection
- Diaphragm use has been demonstrated to provide some protection against cervical gonorrhea, chlamydia, and trichomoniasis (case control, cross sectional studies)
- Diaphragms are not effective to protect women against HIV infection (Padian 08)

- *Nonbarrier Contraception, Surgical Sterilization, and Hysterectomy*
  - Hormonal contraception (e.g., oral contraceptives, Norplant, and Depo-Provera) offer no protection against HIV or other STDs
  - Women who use hormonal or intrauterine contraception, have been surgically sterilized, or have had hysterectomies should still be counseled on the use of condoms for HIV/STI protection

## SPECIAL POPULATIONS

***Pregnant Women***

- *Recommended Screening Tests*
  - Syphilis: all pregnant women at first prenatal visit; high risk (high areas of syphilis morbidity) retested in early third trimester and at delivery. Some states require all women to be screened at delivery
  - Hepatitis B surface antigen (HbsAg): all pregnant women first visit
  - *Neisseria gonorrhoeae:* first visit for women at risk or living in an area of high prevalence
  - *Chlamydia trachomatis:* all women at first prenatal visit and in the third trimester for women at increased risk (i.e., women aged <25 years and women who have a new or more than one sex partner or whose partner has other partners)
  - HIV screening test: encouraged for all pregnant women as routine prenatal test at the first prenatal visit. If high risk retest in 3rd trimester before 36 weeks
  - Bacterial vaginosis (BV): at the first prenatal visit for patients at high risk for preterm labor (history of prematurity). Current evidence does not support universal testing for BV
  - Papanicolaou (Pap) smear: first visit if no Pap smear has been documented during the preceding year
  - Hepatitis C antibodies at the first prenatal visit for women at high risk (intravenous drug users, blood transfusions, organ transplant)

- *Other Concerns (Other STI-related Concerns are to Be Considered as Follows:)*
  - Pregnant women who have either primary genital herpes infection, HBV, primary cytomegalovirus (CMV) infection, or Group B streptococcal infection and women who have syphilis and who are allergic to penicillin may need to be referred to an expert for management
  - HbsAg-positive pregnant women should be reported to the local and/or state health department; household and sexual contacts of HbsAg-positive women should be tested and immunized if negative
  - In the absence of lesions during the third trimester, routine serial culture for herpes simplex virus (HSV) is not indicated for women who have a history of recurrent genital herpes. Prophylactic cesarean section is not indicated for women who do not have active genital lesions at the time of delivery
  - The presence of genital warts is not an indication for cesarean delivery unless size obstructs delivery in labor (rare)

***Adolescents***

- With limited exceptions, all U.S. adolescents can consent to the confidential diagnosis and treatment of STIs. See Table 6.1, p. 19
- All children and adolescents should get HBV vaccine and females 9-26 years old, the HPV vaccine

***Management of Patients Who Have Genital Ulcers***

- In the United States, most young, sexually active patients who have genital ulcers have genital herpes, a smaller percentage have syphilis, or chancroid. Each disease has been associated with an increased risk for HIV infection
- The evaluation of all patients who have genital ulcers should include a serologic test for syphilis and diagnostic evaluation for herpes; in settings where chancroid is prevalent a test for *Haemophilis ducreyi* should be performed. Specific tests (to be used with clinical assessment) for the evaluation of genital ulcers include the following:
  - Serology, dark-field exam or direct immunofluorescence test for *T. pallidum*
  - Culture or antigen test for HSV and
  - Culture for *Haemophilus ducreyi*
- HIV testing should be a) performed in the management of patients who have genital ulcers caused by *T. pallidum* or *H. ducreyi* and b) strongly considered for those who have ulcers caused by HSV

**CHANCROID (SHAN-kroyd)**

***Organism:*** *H. ducreyi*

***Diagnosis:*** Culture on special medium of *H. ducreyi*, or if all of the following criteria are met: a) patient has 1 or more painful ulcers; b) no evidence of syphilis on lab exam after at least 7 days; c) the clinical picture is typical of chancroid and d) test for HSV is negative.

***Treatment: Recommended Regimens***

Azithromycin.....1 g orally in a single dose, OR
Ceftriaxone.....250 mg intramuscularly (IM) in a single dose, OR
Ciprofloxacin.....500 mg orally twice a day for 3 days, OR
Erythromycin base.....500 mg orally three times a day for 7 days.

***Follow-up:*** Re-examine in 3-7 days. If no improvement consider whether a) the diagnosis is correct, b) the patient is coinfected with another STI, c)the patient is infected with HIV, d) the treatment was not taken as instructed, or e) the *H. ducreyi* strain causing the infection is resistant to the prescribed antimicrobial.

- *The time required for complete healing:*
  - Depends on the size of the ulcer; large ulcers may require >2 weeks
  - Healing is slower for some uncircumcised men who have ulcers under the foreskin
  - Resolution of fluctuant lymphadenopathy is slower than that of ulcers and may require drainage, even during otherwise successful therapy
  - Although needle aspiration of buboes is a simple procedure, incision and drainage of buboes may be preferred because of less need for subsequent drainage procedures

***Management of Sex Partners:*** Should be examined and treated regardless of symptoms if they had sexual contact within 10 days of the onset of symptoms

***Special Considerations: Pregnancy.*** The safety of azithromycin for pregnant and lactating women has not been established. Ciprofloxacin is contraindicated during pregnancy and lactation. No adverse effects of chancroid on pregnancy outcome or on the fetus have been reported.

**GENITAL HERPES SIMPLEX VIRAL (HSV) INFECTION (Her-pes)**

Most persons shed the virus intermittently and are unaware that they are infected and are asymptomatic at the time of transmission.

***Organisms:*** HSV-1 and HSV-2

***Diagnosis:*** See complete *2002 CDC Guidelines* or *Contraceptive Technology (18th Edition)*

***Counseling:*** Counseling of these patients should include the following:

- Patients should be advised to abstain from sexual activity when lesions or prodromal symptoms are present and encouraged to inform their sex partners
- Latex condoms, when used consistently and correctly, might reduce the risk for genital herpes, when the infected areas are covered or protected by the condom
- Sexual transmission of HSV can occur during asymptomatic periods
- Daily use of valacyclovir can reduce transmission
- The risk for neonatal infection should be explained to all patients, including men. Childbearing-aged women who have genital herpes should be advised to inform health-care providers who care for them during pregnancy about the HSV infection
- Patients having a first episode of genital herpes should be advised that a) episodic antiviral therapy during recurrent episodes might shorten the duration of lesions and b) suppressive antiviral therapy can ameliorate or prevent recurrent outbreaks
- Patients may be directed to websites: http://www.ashastd.org or www.ihmf.org

***Treatment:*** 5% to 30% of first-episode cases of genital herpes are caused by HSV-1, but clinical recurrences are much less frequent for HSV-1 than HSV-2 genital infection

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- ***HSV, Recommended Regimens for First Clinical Infection***

Acyclovir.....400 mg orally three times a day for 7-10 days, OR
Acyclovir.....200 mg orally five times a day for 7-10 days, OR
Famciclovir.....250 mg orally three times a day for 7-10 days, OR
Valacyclovir.....1.0 g orally twice a day for 7-10 days

- ***HSV, Recommended Regimens for Episodic Recurrent Infection***

Acyclovir.....400 mg orally three times a day for 5 days, OR
Acyclovir.....800 mg orally twice a day for 5 days, OR
Acyclovir.....800 mg orally three times a day for 2 days, OR
Famciclovir.....125 mg orally twice a day for 5 days, OR
Famciclovir.....1000 mg orally twice a day for 1 day, OR
Valacyclovir.....500 mg orally twice a day for 3 days
Valacyclovir.....1.0 g orally once a day for 5 days

- ***HSV, Recommended Regimens for Daily Suppressive Therapy***

Acyclovir.....400 mg orally twice a day, OR
Famciclovir.....250 mg orally twice a day, OR
Valacyclovir.....500 mg orally once a day, OR
Valacyclovir.....1.0 g orally once a day

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- Valacyclovir 500 mg once a day appears less effective than other valacyclovir dosing regimens in patients who have very frequent recurrences (i.e., >10 episodes per year)
- Valacyclovir and famciclovir appear to be comparable to acyclovir in clinical outcome

***Severe Disease:*** IV therapy should be provided for patients who have severe disease or complications necessitating hospitalization, such as disseminated infection, pneumonitis, hepatitis, or complications of the central nervous system (e.g., meningitis or encephalitis)

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- ***HSV, Recommended Regimen for Persons with Severe Disease***

Acyclovir.....5-10 mg/kg body weight IV every 8 hours for 2-7 days until clinical resolution is attained followed by oral therapy to complete 10 days total therapy

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***Special Considerations:***

- *Pregnancy*
  - Available data do not indicate an increased risk for major birth defects in women treated with acyclovir in the first trimester
  - Safety of acyclovir, valacyclovir, and famciclovir Rx in pregnant women not established

- *Perinatal Infection*
  - The risk for transmission to the neonate from an infected mother is high (30% - 50%) among women who acquire genital herpes near the time of delivery and is low (<1%) among women who have a history of recurrent herpes at term and women who acquire genital HSV during the first half of pregnancy
  - Therefore, prevention of neonatal herpes should emphasize prevention of acquisition of genital HSV infection during late pregnancy
  - Susceptible women whose partners have oral or genital HSV infection, or those whose sex partners' infection status is unknown, should be counseled to avoid unprotected genital and oral sexual contact during late pregnancy
  - At the onset of labor, all women should be examined and carefully questioned about whether they have symptoms of HSV. Infants of women who do not have symptoms or signs of HSV infection or its prodrome may be delivered vaginally
  - Cesarean delivery does not completely eliminate the risk for HSV infection in the neonate but is recommended in presence of any lesions (1% recurrent)

**GRANULOMA INGUINALE (DONOVANOSIS)** (gran-u-LO-ma in-gwi-NAL-e, don-o-van-O-sis)

***Organism:*** Klebsiella granulomatis, formerly known as *Calymmatobacterium granulomatis,* is an intracellular, gram-negative bacterium. It is seen rarely in the USA. Presents as a painless, progressive, vascular, ulcerative lesion with regional lymphadenopathy
***Diagnosis:*** Visualization of Donovan bodies from tissue of lesion or biopsy
***Treatment:*** Appears to halt progressive destruction of tissue. Prolonged duration of therapy often required to enable granulation and re-epithelialization of the ulcers. Therapy should be continued at least 3 weeks and until all lesions have healed completely

- ***Granuloma Inguinale, Recommended Regimens***

Doxycycline.....100 mg orally twice a day for a minimum of 3 weeks

- ***Granuloma Inguinale, Alternative Regimens***

Trimethoprim-
sulfamethoxazole.....One double-strength tablet orally twice a day for a minimum of 3 weeks, OR
Ciprofloxacin.....750 mg orally twice a day for a minimum of 3 weeks, OR
Erythromycin base.....500 mg orally four times a day for a minimum of 3 weeks (for use during pregnancy), OR
Azithromycin.....1 g orally per week for at least 3 weeks

NOTE: For any of the above regimens, the addition of an aminoglycoside (gentamicin 1 mg/kg IV every 8 hours) should be considered if lesions do not respond within the first few days of therapy

**LYMPHOGRANULOMA VENEREUM (LGV)** (lim-fo-gran-u-LO-ma ve-nar-E-um)

This is most frequently manifested in heterosexuals as unilateral tender inguinal nodes and in women and homosexual men with proctocolitis, or inflammatory involvement or perirectal or perianal fistulas or strictures
***Organism:*** Invasive strains L1, L2, or L3 of *Chlamydia trachomatis*
***Diagnosis:*** Serological and exclusion of other ulcerative lesions or those with lymphadenopathy.

***Treatment:*** Treatment cures infection and prevents ongoing tissue damage, although tissue reaction can result in scarring. Buboes may require aspiration through intact skin or incision and drainage to prevent the formation of inguinal/femoral ulcerations.

- ***LGV, Recommended Regimen***

Doxycycline.....100 mg orally twice a day for 21 days OR

- ***Alternative Regimen***

Erythromycin base.....500 mg orally four times a day for 21 days

## SYPHILIS (SIF-i-lis)

***Organism:*** *Treponema pallidum* (tre-po-NE-ma PAL-e-dum)
***Diagnosis:*** See most recent CDC Guidelines or ***Contraceptive Technology***
***Treatment:***

- Parenteral penicillin G is preferred drug for Rx of all stages of syphilis. The preparation(s) used (i.e., benzathine, aqueous procaine, or aqueous crystalline), the dosage, and the length of Rx depend on the stage and clinical manifestations of disease
- Parenteral penicillin G is the only therapy with documented efficacy for syphilis during pregnancy. Patients who report a penicillin allergy, including pregnant women with syphilis in any stage and patients with neurosyphilis, should be desensitized and treated with penicillin
- The Jarisch-Herxheimer reaction is an acute febrile reaction often accompanied by headache, myalgia, and other symptoms that might occur within the first 24 hours after any therapy for syphilis; patients should be advised of this possible adverse reaction

### PRIMARY, SECONDARY AND EARLY LATENT SYPHILIS

- ***Recommended Regimen for Adults***

Benzathine penicillin G..... 2.4 million units IM in a single dose

***Management Considerations:*** All patients who have syphilis should be tested for HIV infection. In areas in which the prevalence of HIV is high, patients who have primary syphilis should be retested for HIV after 3 months if the first HIV test result was negative
***Follow-up:*** Serologic test titers may decline more slowly for patients who previously had syphilis. Patients should be reexamined clinically and serologically at both 6 months and 12 months; also see complete *2006 CDC Guidelines* for more detail
***Management of Sex Partners:*** *Sexual transmission of* T. pallidum *has occurred only when mucocutaneous syphilitic lesions are present;* such manifestations are uncommon after the first year of infection. However, persons exposed sexually to a patient who has syphilis in any stage should be evaluated clinically and, according to CDC, serologically
***Special Considerations***

- *Penicillin Allergy:* Nonpregnant penicillin-allergic patients who have primary or secondary syphilis should be treated with one of the following regimens. Close follow-up of such patients is essential. Limited clinical studies suggest that ceftriaxone may be effective for early syphilis. The optional dose and duration of therapy have not been defined, however, some specialists recommend 1 gm daily IM or IV for 8-10 days

- ***Recommended Regimens***

Doxycycline.....100 mg orally twice a day for 2 weeks, OR
Tetracycline.....500 mg orally four times a day for 2 weeks

- Pregnant patients who are allergic to penicillin should be desensitized, if necessary, and treated with penicillin.

**LATENT SYPHILIS:**
See most recent CDC Guidelines
**TERTIARY SYPHILIS:**
See most recent CDC Guidelines

## DISEASES CHARACTERIZED BY URETHRITIS AND CERVICITIS

***Management of Patients Who Have Nongonococcal Urethritis***
***Diagnosis:*** Testing for chlamydia and gonorrhea is strongly recommended because of the increased utility and availability of highly sensitive and specific testing methods and because a specific diagnosis might improve compliance and partner notification
***Treatment:***

- ***Nongonococcal Urethritis, Recommended Regimens***

Azithromycin.....1 g orally in a single dose, OR
Doxycycline.....100 mg orally twice a day for 7 days

- ***Nongonococcal Urethritis, Alternative Regimens***

Erythromycin base.....500 mg orally four times a day for 7 days, OR
Erythromycin ethylsuccinate....800 mg orally four times a day for 7 days, OR
Ofloxacin.....300 mg twice a day for 7 days, OR
Levofloxacin.....500 mg orally once daily for 7 days

***Follow-up:*** If symptoms persist, patients should be instructed to return for reevaluation and to abstain from sexual intercourse even if they have completed the prescribed therapy
***Partner Referral:*** Patients should refer all sex partners within the preceding 60 days for evaluation and treatment

- ***Recurrent/Persistent Urethritis, Recommended Treatment***

Retreat with initial regimen if noncompliant or reexposed. Otherwise, do culture for T. vaginalis
Metronidazole.....2 g orally in a single dose, OR
Tinidazole.....2 g orally in single dose, OR
Azithromycin.....1 g orally in a single dose (if not used intially)

## CHLAMYDIAL INFECTION IN ADOLESCENTS AND ADULTS

Several important sequelae can result from *Chlamydia trachomatis* (kla-MID-e-a tra-KO-ma-tis) infection in women; the most serious of these include PID, ectopic pregnancy, and infertility. Some women who have apparently uncomplicated cervical infection already have subclinical upper reproductive tract infection. Chlamydial infection is much more common in women under age 25 than in older women. Asymptomatic older women need not be screened unless they have risk factors (e.g. new partner), but sexually-active young women should be.
***Diagnosis:*** See complete *2006 CDC Guidelines*
***Treatment:***

- Treatment of infected patients prevents transmission to sex partners and, for infected pregnant women, might prevent transmission to infants during birth
- Treatment of sex partners helps to prevent reinfection of the index patient and infection of other partners
- Coinfection with *C. trachomatis* often occurs among patients who have gonococcal infection; therefore, presumptive treatment of such patients for chlamydia is appropriate (see GONOCOCCAL INFECTION, Dual Therapy for Gonococcal and Chlamydial Infection, p 153)
- The following recommended treatment regimens and the alternative regimens cure infection and usually relieve symptoms:

- ***Chlamydia Infection, Recommended Regimens***

Azithromycin.....1 g orally in a single dose, OR (equally effective)
Doxycycline.....100 mg orally twice a day for 7 days

- ***Chlamydia Infection, Alternative Regimens***

Erythromycin base.....500 mg orally four times a day for 7 days, OR
Erythromycin ethylsuccinate...800 mg orally four times a day for 7 days, OR
Ofloxacin.....300 mg orally twice a day for 7 days, OR
Levofloxacin.....500 mg orally once daily for 7 days

***Follow-up:*** Patients do not need to be retested for chlamydia after completing treatment with doxycycline or azithromycin unless symptoms persist or reinfection is suspected because these therapies are highly efficacious. Rescreening is recommended for chlamydia infection 3 months after treatment due to high prevalence of reinfection, especially for adolescents

***Management of Sex Partners:*** Patients should be instructed to refer their sex partners for evaluation, testing, and treatment, if they had sexual contact with the patient during the 60 days preceding onset of symptoms in the patient or diagnosis of chlamydia, and the most recent contact should be tested even if > 60 days ago

***Special Considerations:***

- *Pregnancy:*
  - Doxycycline, ofloxacin and levofloxacin are contraindicated for pregnant women
  - Clinical experience and studies suggest azithromycin is safe and effective
  - Repeat testing, preferably NAAT, 3 weeks after completion of therapy with the following regimens is recommended because a) sequelae to mom and infant b) frequent side effects of erythromycin may discourage patient compliance

- ***Recommended Regimens for Pregnant Women***

Azithromycin.....1 g orally in single dose OR
Amoxicillin.....500 mg orally three times a day for 7 days.

- ***Alternative Regimens for Pregnant Women***

Erythromycin base.....500 mg orally four times a day for 7 days, OR
Erythromycin base.....250 mg orally four times a day for 14 days, OR
Erythromycin ethylsuccinate.....800 mg orally four times a day for 7 days, OR
Erythromycin ethylsuccinate.....400 mg orally four times a day for 14 days, OR

NOTE: Erythromycin estolate is contraindicated during pregnancy because of drug-related hepatotoxicity.

## GONOCOCCAL INFECTION

### DUAL THERAPY FOR GONOCOCCAL AND CHLAMYDIAL INFECTIONS

Patients infected with *N. gonorrhoeae* often are coinfected with *C. trachomatis*; this finding led to the recommendation that patients treated for gonococcal infection also be treated routinely with a regimen effective against uncomplicated genital *C. trachomatis* infection. CDC no longer recommends use of fluoroquinolones for treatment of gonococcal infections or PID

***Uncomplicated Gonococcal Infections of the Cervix, Urethra, and Rectum***

- ***Recommended Regimens***

Cefixime.....400 mg orally in a single dose or 400 mg by suspension (200mg/5ml)
Ceftriaxone.....125 mg IM in a single dose, AND
TREATMENT FOR CHLAMYDIA IF CHLAMYDIAL INFECTION NOT RULED OUT
Azithromycin.....1 g orally in a single dose, if chlamydia not ruled out OR
Doxycycline.....100 mg orally twice a day for 7 days, if chlamydia not ruled out

***Uncomplicated Gonococcal Infections of the Cervix, Urethra, and Rectum***

- ***Alternative Regimens***

Spectinomycin.....2 g IM in a single dose. Spectinomycin is currently not available in the U.S.

Single-dose cephalosporin....regimens other than cefritaxone 125 mg IM and cefixime 400 mg include a) ceftizoxime 500 mg IM, b) cefotaxime 500 mg IM, and c) cefoxitin 2 g IM with probenicid 1 g orally

- Many other antimicrobials are active against *N. gonorrhoeae*
- Azithromycin 2 g orally is effective against uncomplicated gonococcal infection, but it is expensive and causes gastrointestinal distress
- An oral dose of 1 g azithromycin is not recommended

***Uncomplicated Gonococcal Infection of the Pharynx***

- Gonococcal infections of the pharynx are more difficult to eradicate than infections at urogenital and anorectal sites
- Few antigonococcal regimens can reliably cure such infections >90% of the time
- Although chlamydial coinfection of the pharynx is unusual, coinfection at genital sites sometimes occurs. Therefore, treatment for both gonorrhea and chlamydia is suggested

- ***Recommended Regimen***

Ceftriaxone.....125 mg IM in a single dose, PLUS
TREATMENT FOR CHLAMYDIA IF CHLAMYDIA INFECTION NOT RULED OUT
Doxycycline.....100 mg orally twice a day for 7 days, if chlamydia not ruled out

***Management of Sex Partners:*** All sex partners of patients who have *N. gonorrhea* infection should be evaluated and treated for *N. gonorrhea* and *C. trachomatis* infections if their last sexual contact with the patient was within 60 days before onset of symptoms or diagnosis. Most recent should be notified even if > 60 days prior

***Special Considerations:***

- Pregnant women should not be treated with quinolones or tetracyclines
- Pregnant women infected with *N. gonorrhoeae* should be treated with a recommended or alternate cephalosporin
- Women who cannot tolerate a cephalosporin should be administered a single 2-g dose of spectinomycin IM
- Either azithromycin or amoxicillin is recommended for treatment of presumptive or diagnosed *C. trachomatis* infection during pregnancy (see CHLAMYDIAL INFECTION, p. 152)

## DISEASES CHARACTERIZED BY VAGINAL DISCHARGE

***Have Vaginal Infections:***

- Vaginitis is usually characterized by a vaginal discharge or vulvar itching and irritation; a vaginal odor may be present
- The three diseases most frequently associated with vaginal discharge are trichomoniasis (caused by *T. vaginalis*), BV (caused by a replacement of the normal vaginal flora by an overgrowth of anaerobic microorganisms and *Gardnerella vaginalis*), and candidiasis (usually caused by *Candida albicans*)
- Mucopurulent cervicitis caused by *C. trachomatis* or *N. gonorrhoeae* can sometimes cause vaginal discharge
- Vaginitis is diagnosed by pH and microscopic examination of fresh samples of the discharge
- The pH of the vaginal secretions can be determined by narrow-range pH paper for the elevated pH typical of BV or trichomoniasis (i.e., pH of >4.5)
- One way to examine the discharge is to dilute a sample in one to two drops of 0.9% normal saline solution on one slide and 10% potassium hydroxide (KOH) solution on a second slide. Always prepare saline slide first
- An amine odor detected immediately after applying KOH suggests BV
- A cover slip is placed on each slide, which is then examined under a microscope at low and high-dry power. The motile *T. vaginalis* or the clue cells of BV usually are identified easily in the saline specimen
- The yeast or pseudohyphae of *Candida* species are more easily identified in the KOH specimen
- The presence of objective signs of vulvar inflammation in the absence of vaginal pathogens, along with a minimal amount of discharge, suggests the possibility of mechanical, chemical, allergic, or other noninfectious irritation of the vulva
- Culture for *T. vaginalis* is more sensitive than microscopic examination
- Laboratory testing fails to identify the cause of vaginitis among a minority of women

### BACTERIAL VAGINOSIS (BV)

- BV is a clinical syndrome resulting from replacement of the normal $H_2O_2$ producing *Lactobacillus* sp. in the vagina with high concentrations of anaerobic bacteria (e.g., *Prevotella* sp. and *Mobiluncus* sp.), *G. vaginalis*, and *Mycoplasma hominis*
- BV is the most prevalent cause of vaginal discharge or malodor
- Half of women whose illnesses meet the clinical criteria for BV are asymptomatic
- Treatment of male sex partner has not been beneficial in preventing recurrence

***Diagnostic Considerations:*** BV can be diagnosed by the use of clinical criteria meeting three of the following symptoms or signs:

a. A homogeneous, white, noninflammatory discharge that smoothly coats the vaginal walls
b. The presence of clue cells on microscopic examination
c. A pH of vaginal fluid >4.5
d. A fishy odor of vaginal discharge before or after addition of 10% KOH (i.e., the whiff test)

***Treatment:*** The principal goal of therapy in nonpregnant women is to relieve vaginal symptoms and signs of infection. All women **with** symptoms require treatment, regardless of pregnancy status

- ***BV, Recommended Regimens for Nonpregnant Women***

Metronidazole.....500 mg orally twice a day for 7 days, OR
Clindamycin cream.....2%, one full applicator (5 g) intravaginally at bedtime for 7 days OR
Metronidazole gel.....0.75%, one full applicator (5 g) intravaginally, once daily for 5 days OR

- Patients should be advised to avoid consuming alcohol during treatment with metronidazole and for 24 hours thereafter. Clindamycin cream is oil-based and might weaken latex condoms and diaphragms for 5 days after use

- ***BV, Alternative Regimens***

Clindamycin.....300 mg orally bid x 7 days OR
Clindamycin ovules.....100 mg intravaginally qhs x 3 days

Recommended metronidazole regimens are equally efficacious. The vaginal clindamycin cream appears to be less efficacious than the metronidazole regimens

- Metronidazole 2 g single-dose therapy is an alternative regimen because of its lower efficacy for BV
- FDA has approved both metronidazole 750-mg extended release tablets once daily for 7 days and a single dose of clindamycin vaginal cream. However, data concerning clinical equivalency of these regimens with other regimens have not been published.

***Follow-up:*** Follow-up visits are unnecessary if symptoms resolve. Recurrence is not unusual

- Because treatment of BV in high-risk pregnant women who are asymptomatic might prevent adverse pregnancy outcomes, a follow-up evaluation, at 1 month after completion of treatment, should be considered

***Management of Sex Partners:*** Routine treatment of sex partners is not recommended

***Special Considerations:***

- *Allergy or Intolerance to the Recommended Therapy:*
  - Clindamycin cream is preferred in case of allergy or intolerance to metronidazole. Metronidazole gel can be considered for patients who do not tolerate systemic metronidazole, but patients allergic to oral metronidazole should not be administered metronidazole vaginally
- *Pregnancy:*
  - BV has been associated with adverse pregnancy outcomes (i.e., premature rupture of the membranes, preterm labor, and preterm birth)
  - Organisms found in increased concentration in BV also are frequently present in postpartum or post-cesarean endometritis
  - Treat all symptomatic pregnant women when diagnosed
  - Treatment of BV in high-risk pregnant women (i.e., those who have previously delivered a premature infant) who are asymptomatic might reduce preterm delivery. However, the optimal treatment regimens have not been established. Some specialists screen and treat those with BV at first prenatal visit and prefer oral therapy
  - The recommended regimen is metronidazole 250 mg orally three times a day for 7 days OR metronidazole 500 mg orally twice a day for 7 days OR clindamycin 300 mg orally twice daily for 7 days
  - Low-risk pregnant women (i.e., those who previously have not had a premature delivery) who have symptomatic BV should be treated to relieve symptoms.
  - Data are limited concerning the use of metronidazole vaginal gel during pregnancy. Use of clindamycin vaginal cream during the second half of pregnancy is not recommended because three randomized trials indicated an increase in adverse events
  - Multiple studies have not demonstrated an association between metronidazole use during pregnancy and teratogenicity in newborns

***Other:*** The bacterial flora that characterize BV have been recovered from the endometria and salpinges of women who have PID

## TRICHOMONIASIS

***Diagnosis:***

- Trichomoniasis is caused by the protozoan *T. vaginalis,* easily identified on a wet smear Most men who are infected do not have symptoms of infection, although a minority of men have nongonococcal urethritis
- Many women do have symptoms of infection, characteristically a diffuse, malodorous, yellow-green discharge with vulvar irritation; many women have fewer symptoms
- Vaginal trichomoniasis might be associated with adverse pregnancy outcomes, particularly premature rupture of the membranes and preterm delivery

***Treatment:***

- ***Trichomoniasis, Recommended Regimen***

Metronidazole.....2 g orally in a single dose, OR
Tinidazole.....2 g orally in a single dose

- ***Trichomoniasis, Alternative Regimen***

Metronidazole.....500 mg twice a day for 7 days

- In randomized clinical trials, the recommended metronidazole and tinidazole regimens have resulted in cure rates of approximately 90% - 95%; ensuring treatment of sex partners might increase the cure rate. Treatment of patients and sex partners results in relief of symptoms, microbiologic cure, and reduction of transmission
- Metronidazole gel is < 50% effective
- Patients should be advised to avoid alcohol through 24 hours after completion of Rx with metronidazole and 72 hours after Rx with tinidazole

***Follow-up:***

- Unnecessary for men and women who become asymptomatic after treatment or who are initially asymptomatic
- Infections with strains of *T. vaginalis* that have diminished susceptibility to metronidazole can occur; however, most of these organisms respond to higher doses of metronidazole or tinidazole
- If treatment failure occurs with metronidazole, the patient should be retreated with metronidazole 500 mg twice a day for 7 days or tinidazole
- If treatment failure occurs repeatedly, the patient should be treated with a single, 2g dose of metronidazole or tinidazole once a day for 3-5 days

***Management of Sex Partners:*** Routine Rx recommended avoid intercourse until Rx is complete and both partners are assymptomatic

***Special Considerations:***

- *Allergy, Intolerance, or Adverse Reactions:* Effective alternatives to therapy with metronidazole or tinidazole are not available. Patients who are allergic to this class of drugs can be managed by desensitization
- *Pregnancy:* Patients may be treated with 2 g of metronidazole in a single dose; see guidelines
- *HIV Infection:* Patients who have trichomoniasis and also are infected with HIV should receive the same treatment regimen as those who are HIV negative

## VULVOVAGINAL CANDIDIASIS (VVC)

- Vulvovaginal yeast infections are caused by *C. albicans* or, occasionally, by other *Candida* sp. or other yeasts
- An estimated 75% of women will have at least one episode of VVC
- Typical symptoms of VVC include pruritus and vaginal discharge
- Other symptoms may include vaginal soreness, vulvar burning, dyspareunia, and external dysuria
- None of these symptoms is specific for VVC

***Diagnostic Considerations:***

- A diagnosis of *Candida* vaginitis is suggested clinically by pruritus and erythema in the vulvo-vaginal area; a white discharge may occur, as may vulvar edema
- The diagnosis can be made in a woman who has signs and symptoms of vaginitis, and when either a) a wet preparation or Gram stain of vaginal discharge demonstrates yeasts or pseudohyphae or b) a culture or other test yields a positive result for a yeast species
- If culture cannot be done and KOH test is negative, empiric Rx can be considered for symptomatic women
- *Candida* vaginitis is associated with a normal vaginal pH (<4.5)
- Use of 10% KOH in wet preparations improves the visualization of yeast and mycelia by disrupting cellular material that might obscure the yeast or pseudohyphae
- Identifying *Candida* by culture in the absence of symptoms should not lead to treatment because 10%-20% of women usually harbor *Candida* sp. and other yeasts in the vagina. VVC can occur concomitantly with STIs

***Treatment:*** Topical formulations effectively treat VVC. The topically applied azole drugs are more effective than nystatin. Treatment with azoles results in relief of symptoms and negative cultures among 80%-90% of patients who complete therapy

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- ***VVC, Recommended Regimens***
- *Intravaginal agents:*

Butoconazole*.....2% cream 5 g intravaginally for 3 days, **OR**
Butoconazole.....2% cream 5g (butoconazole 1-sustained release), single vaginal application
Clotrimazole*.....1% cream 5 g intravaginally for 7-14 days, **OR**
Clotrimazole.....100-mg vaginal tablet for 7 days, **OR**
Clotrimazole.....100-mg vaginal tablet, two tablets for 3 days, **OR**
Miconazole*.....2% cream 5 g intravaginally for 7 days, **OR**
Miconazole*.....200-mg vaginal suppository, one suppository for 3 days, **OR**
Miconazole*.....100-mg vaginal suppository, one suppository for 7 days, **OR**
Miconazole*.....1200-mg vaginal suppository, one time dose, **OR**
Nystatin.....100,000-u vaginal tablet, one tablet for 14 days, **OR**
Tioconazole*.....6.5% ointment 5 g intravaginally in a single application, **OR**
Terconazole.....0.4% cream 5 g intravaginally for 7 days, **OR**
Terconazole.....0.8% cream 5 g intravaginally for 3 days, **OR**
Terconazole.....80-mg vaginal suppository, one suppository for 3 days, **OR**

- *Oral agent:*

Fluconazole.....150-mg oral tablet, one tablet in single dose.

* *Over-the-counter preparations*

These creams and suppositories are oil-based and may weaken latex condoms and diaphragms

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***Follow-up:*** Patients should be instructed to return for follow-up visits only if symptoms persist or recur

***Management of Sex Partners:*** None; VVC usually is not acquired through sexual intercourse

***Special Considerations:***

- *Pregnancy:* VVC often occurs during pregnancy. Only topical azole therapies applied for 7 days should be used to treat pregnant women.
- *HIV Infection:* Based on available evidence, therapy is same as seronegative women

## PELVIC INFLAMMATORY DISEASE (PID) (see Table 13.1, page 39)

- PID comprises a spectrum of inflammatory disorders of the upper female genital tract, including any combination of endometritis, salpingitis, tuboovarian abscess, and pelvic peritonitis
- Sexually transmitted organisms, especially *N. gonorrhoeae* and *C. trachomatis*, are implicated in most cases; however, microorganisms that can be part of the vaginal flora (e.g., anaerobes, *G. vaginalis*, *H. influenzae*, enteric gram negative rods, and *Streptococcus agalactiae*) also can cause PID
- In addition, CMV, *M. hominis* and *U. urealyticum* may also be etiologic agents

***Diagnostic Considerations:*** See complete *2006 CDC Guidelines (www.cdc.gov)*. Empiric treatment should be initiated in sexually active young women and others at risk for STIs if they are experiencing pelvic or lower abdominal pain, if no other cause can be identified and if **ONE** of the following minimum criteria are present on pelvic exam:

- cervical motion tenderness **OR**
- uterine tenderness **OR**
- adenexal tenderness

***Treatment:*** Must provide empiric, broad-spectrum coverage of likely pathogens
Antimicrobial coverage should include *N. gonorrhea*, *C. trachomatis*

- Suggested *criteria for* ***HOSPITALIZATION*** *decision based on discretion of HCP*
- Surgical emergencies such as appendicitis cannot be excluded
  - Patient is pregnant
  - Patient does not respond clinically to oral antimicrobial therapy
  - Patient is unable to follow or tolerate an outpatient oral regimen
  - Patient has severe illness, nausea and vomiting, or high fever
  - Patient has a tuboovarian abscess

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- ***PID, Parenteral Regimen A***

Cefotetan.....2 g IV every 12 hours, **OR**
Cefoxitin.....2 g IV every 6 hours, **PLUS**
Doxycycline.....100 mg IV or orally every 12 hours

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- Because of pain associated with infusion, doxycycline should be administered orally when possible, even when the patient is hospitalized
- Both oral and IV administration of doxycycline provide similar bioavailability
- When tuboovarian abscess is present, many health-care providers use clindamycin or metronidazole with doxycycline for continued therapy rather than doxycycline alone, because it provides more effective anaerobic coverage

- ***PID, Parenteral Regimen B***

Clindamycin.....900 mg IV every 8 hours, **PLUS**

Gentamicin.....loading dose IV or IM (2 mg/kg of body weight) followed by a maintenance dose (1.5 mg/kg) every 8 hours. Single daily dosing may be substituted.

- Although use of a single daily dose of gentamicin has not been evaluated for the treatment of PID, it is efficacious in analogous situations
- Parenteral therapy may be discontinued 24 hours after a patient improves clinically, and continuing oral therapy should consist of doxycycline 100 mg orally twice a day or clindamycin 450 mg orally four times a day to complete a total of 14 days of therapy
- When tuboovarian abscess is present, many healthcare providers use clindamycin for continued therapy rather than doxycycline because clindamycin provides more effective anaerobic coverage

- ***PID, Alternative Parenteral Regimens:*** Limited data support the use of other parenteral regimens, but the following has been investigated in at least one clinical trial, and it has broad-spectrum coverage.

Ampicillin/Sulbactam.....3 g IV every 6 hours, PLUS doxycycline 100 mg IV / orally every 12 hours **OR**

***Oral Treatment:*** Can be considered for mild to moderately severe acute PID. Patients who do not respond to oral therapy within 72 hours should be reevaluated to confirm the diagnosis and be administered parenteral therapy on either an outpatient or inpatient basis.

- ***PID, Recommended Oral Regimen***

Ceftriaxone.....250 mg IM once, **OR**

Cefoxitin.....2 g IM plus probenecid, 1 g orally in a single dose concurrently once, **OR**

Other parenteral third-generation cephalosporin (e.g.,ceftizoxime or cefotaxime), **PLUS**

Doxycycline.....100 mg orally twice a day for 14 days with or without metronidazole 500 mg orally twice daily for 14 days.

- ***PID, Alternative Oral Regimens:*** If parenteral cephalosporin therapy is not feasible, use of fluoroquinolones (levofloxacin 500 mg orally once daily or ofloxacin 400 mg twice daily for 14 days) with or without metronidazole (500 mg orally twice daily for 14 days) may be considered if the community prevalence and individual risk (see "Gonococcal Infections in Adolescents and Adults" in Sexually Transmitted Disease Treatment Guidelines, 2006) of gonorrhea is low. Tests for gonorrhea must be performed prior to instituting therapy and the patient managed as follows if the test is positive:
  - If NAAT test is positive, parenteral cephalosporin is recommended
  - If culture for gonorrhea is positive, treatment should be based on results of antimicrobial susceptibility. If isolate is QRNG, or antimicrobial suseptibility can't be assessed, parenteral cephalosporin is recommended

***Follow-up:***

- Patients receiving oral or parenteral Rx should demonstrate substantial clinical improvement (i.e., defervescence; reduction in direct or rebound abdominal tenderness; and reduction in uterine, adnexal, and Cx motion tenderness) within 3 days after initiation of Rx
- Patients who do not improve within 3 days usually require additional diagnostic tests, surgical intervention, or both

***Special Considerations:***

- *Pregnancy:* Pregnant women who have suspected PID should be hospitalized and treated with parenteral antibiotics.

## HUMAN PAPILLOMAVIRUS INFECTION (HPV)

***Genital Warts: Vaccine now available.*** ***See page 145***

- More than 30 types of HPV can infect the genital tract. Most HPV infections are asymptomatic, subclinical, or unrecognized. Visible genital warts usually are caused by HPV types 6 or 11. Other HPV types in the anogenital region (i.e., types 16, 18, 31, 33, and 35) have been strongly associated with cervical dysplasia
- HPV types 16, 18, 31, 33, and 35 are found occasionally in visible genital warts and have been associated with external genital (i.e., vulvar, penile, and anal) squamous intraepithelial neoplasia (i.e., squamous cell carcinoma in situ, bowenoid papulosis, erythroplasia of Queyrat, or Bowen's disease of the genitalia). These HPV types have been associated with vaginal, anal, and cervical intraepithelial dysplasia and squamous cell carcinoma. Patients who have visible genital warts can be infected simultaneously with multiple HPV types

***Treatment:***

- The primary goal of treating visible genital warts is the removal of symptomatic warts
- Treatment can induce wart-free periods in most patients. Genital warts often are asymptomatic
- **No evidence indicates that currently available treatments eradicate or affect the natural history of HPV infection.** The removal of warts may or may not decrease infectivity
- If left untreated, visible genital warts may resolve on their own, remain unchanged, or increase in size or number. No evidence indicates that presence of visible warts or their treatment is associated with the development of cervical cancer

***Regimens:***

- Treatment of genital warts should be guided by the patient's preference, the available resources, and the experience of the health-care provider.
- None of the available treatments is superior to other treatments, and no single treatment is ideal for all circumstances. The treatment modality should be changed if a patient has not improved substantially. The majority respond within 3 months of therapy

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- ***External Genital Warts, Recommended Treatments:***
- *Patient-Applied*

Podofilox.....0.5% solution or gel OR
Imiquimod.....5% cream

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- Patients may apply **podofilox** solution with a cotton swab, or podofilox gel with a finger, to visible genital warts twice a day for 3 days, followed by 4 days of no therapy
- This cycle may be repeated as necessary for a total of four cycles
- The total wart area treated should not exceed 10 $cm^2$, and a total volume of podofilox should not exceed 0.5 mL per day
- If possible, the health-care provider should apply the initial treatment to demonstrate the proper application technique and identify which warts should be treated.
- The safety of podofilox during pregnancy has not been established.
- Patients should apply **imiquimod** cream with a finger at bedtime, three times a week for as long as 16 weeks
- The treatment area should be washed with mild soap and water 6-10 hours after the application
- The safety of imiquimod during pregnancy has not been established

- *Provider-Administered:*
  Cryotherapy with liquid nitrogen or cryoprobe. Repeat applications every 1 to 2 weeks **OR** Trichloroacetic acid (TCA) or BCA 80%-90%. May place petroleum jelly around wart to reduce spread of medication to normal mucosa. Apply a small amount only to warts and allow to dry, at which time a white "frosting" develops; powder with talc or $NaHCO_3$ to remove unreacted acid if an excess amount is applied. Repeat weekly if necessary. **OR**
  Podophyllin resin.....10%-25% in tincture of benzoin
- A small amount should be applied to each wart and allowed to air dry
- To avoid the possibility of complications associated with systemic absorption and toxicity, application should be limited to <0.5 mL of podophyllin or <10 $cm^2$ of warts per session and no open wounds should exist nearby
- Some experts suggest that the preparation should be thoroughly washed off 1-4 hours after application to reduce local irritation. Repeat weekly if necessary
- *The safety of podophyllin during pregnancy has not been established*
- *Surgical removal* by tangential scissor excision, tangential shave excision, curettage, or electrosurgery

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- ***External Genital Warts, Alternative Treatments (Provider administered)***

Intra-lesional interferon **OR**
Laser surgery

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- ***Cervical Warts***

For women who have exophytic cervical warts, high-grade squamous intraepithelial lesions (SIL) must be excluded before treatment is begun. Management of exophytic cervical warts should include consultation with an expert

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- ***Vaginal Warts, Recommended Treatment***

*Cryotherapy with liquid nitrogen.* The use of a cryoprobe in the vagina is not recommended because of the risk for vaginal perforation and fistula formation. **OR**
*TCA or BCA 80%-90%* applied only to warts. Repeat weekly if necessary.

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- ***Urethral Meatus Warts, Recommended Treatment***

*Cryotherapy* with liquid nitrogen **OR**
*Podophyllin 10%-25%* in tincture of benzoin. The treatment area must be dry before contact with normal mucosa. Podophyllin may be applied weekly if necessary. *The safety of podophyllin during pregnancy has not been established.*

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- ***Anal Warts, Recommended Treatment***

*Cryotherapy* with liquid nitrogen **OR**
*TCA or BCA 80%-90%* applied to warts. Apply a small amount only to warts and allow to dry, at which time a white "frosting" develops; powder with talc or sodium bicarbonate (i.e., baking soda) to remove unreacted acid if an excess amount is applied. Repeat weekly if necessary. May place petroleum jelly around wart to reduce spread of medication to normal mucosa **OR**
*Surgical removal*
- Management of warts on rectal mucosa should be referred to an expert

***Follow-up:*** After visible genital warts have cleared, a follow-up might be helpful
***Management of Sex Partners:*** None. Examination of sex partners is not necessary for the management of genital warts because the role of reinfection is probably minimal and, in the absence of curative therapy, treatment to reduce transmission is not realistic
***Special Considerations:***

- *Pregnancy:* Imiquimod, podophyllin, and podofilox should not be used during pregnancy. Because genital warts can proliferate and become friable during pregnancy, many experts advocate their removal during pregnancy. HPV types 6 and 11 can cause laryngeal papillomatosis in infants and children. Vaginal delivery not contraindicated unless lesion size obstructive in labor (rare) or would result in excessive bleeding. The route of transmission (i.e., transplacental, perinatal, or postnatal) is not completely understood

## VACCINE-PREVENTABLE STIs

One of the most effective means of preventing the transmission of STIs is preexposure immunization. Currently licensed vaccines for the prevention of STIs include those for hepatitis A and hepatitis B. Clinical development and trials are underway for vaccines against a number of other STIs, including HIV and HSV. As more vaccines become available, immunization possibly will become one of the most widespread methods used to prevent STIs. Quadrivalent HPV (6, 11, 16, 18) vaccine could prevent 90% of genital warts in young women who receive it prior to sexual exposure.

## ECTOPARASITIC INFECTIONS

### PEDICULOSIS PUBIS

Patients who have pediculosis pubis (i.e., pubic lice) usually seek medical attention because of pruritus. Such patients also usually notice lice or nits on their pubic hair. Usually sexually transmitted

***Treatment:***

- ***Pediculosis Pubis, Recommended Regimens***

Permethrin.....1% creme rinse applied to affected areas and washed off after 10 minutes **OR**

Pyrethrins with piperonyl butoxide applied to the affected area and washed off after 10 minutes.

*See 2006 guidelines for alternative regimens*

***Other Management Considerations:***

- The recommended regimens should not be applied to the eyes. Pediculosis of the eyelashes should be treated by applying occlusive ophthalmic ointment to the eyelid margins twice a day for 10 days
- Bedding and clothing should be decontaminated (either machine-washed and machine-dried using the heat cycle or drycleaned) or removed from body contact for at least 72 hrs
- Fumigation of living areas is not necessary

***Follow-up:*** Patients should be evaluated after 1 week if symptoms persist. Retreatment may be necessary if lice are found or if eggs are observed at the hairskin junction. Patients who do not respond to one of the recommended regimens should be retreated with an alternative regimen
***Management of Sex Partners:*** Sex partners within the last month should be treated
***Special Considerations:***

- *Pregnancy:* Pregnant and lactating women should be treated with either permethrin or pyrethrins with piperonyl butoxide

## SCABIES

- Predominant symptoms is pruritus; sensitization takes several weeks to develop; pruritus might occur within 24 hours after a subsequent reinfestation
- Scabies in adults may be sexually transmitted, although scabies in children usually is not

***• Scabies, Recommended Regimen***

Permethrin cream.....(5%) applied to all areas of the body from the neck down and washed off after 8-14 hours. **OR**

Ivermectin.....200 mcg/kg orally, repeated in 2 weeks

***• Scabies, Alternative Regimens***

Lindane.....(1%) 1 oz. of lotion or 30 g of cream applied thinly to all areas of the body from the neck down and thoroughly washed off after 8 hours

- Lindane should not be used immediately after a bath, and it should not be used by a) persons who have extensive dermatitis, b) pregnant or lactating women, and c) children aged <2 years. Not first-line because of toxicity

***Other Management Considerations:*** Bedding and clothing should be decontaminated (i.e., either machine-washed or machine-dried using the hot cycle or dry-cleaned) or removed from body contact for at least 72 hours. Fumigation of living areas is unnecessary

***Follow-up:*** Pruritus may persist for several weeks. Some experts recommend retreatment after 1-2 weeks for patients who are still symptomatic; other experts recommend retreatment only if live mites are observed. Patients who do not respond should be retreated with an alternative regimen

***Management of Sex Partners and Household Contacts:*** Both sexual and close personal or household contacts within the preceding month should be examined and treated

## SEXUAL ASSAULT AND STIs: Adults and Adolescents

***Evaluation for Sexually Transmitted Infections***

- *Initial Examination* - (See inside back cover)
- *Follow-up Examination after Assault*
  - Examination for STIs should be repeated 2 weeks after assault (see inside back cover)
  - Serologic tests for syphilis and HIV infection should be repeated 6, 12, and 24 weeks after the assault if initial test results were negative
- Prophylaxis: Many experts recommend routine preventive therapy after a sexual assault. The prophylactic regimen suggested is on inside back cover
- An empiric antimicrobial regimen for chlamydia, gonorrhea, trichomonas, and BV should be administered (See inside back cover)

***Other Management Considerations:***

At the initial examination and, if indicated, at follow-up, patients should be counseled about:

- Risk for pregnancy and possible use of emergency contraception
- Symptoms of STIs and the need for immediate examination if symptoms occur
- Abstinence from sexual intercourse until STI prophylactic treatment is completed

***Risk for Acquiring HIV Infection:***

- Although HIV antibody seroconversion has been reported among persons whose only known risk factor was sexual assault or sexual abuse, the risk for acquiring HIV infection through sexual assault is low and depends on many factors
- These factors may include the type of sexual intercourse (i.e., oral, vaginal, or anal); presence of oral, vaginal or anal trauma; site of exposure to ejaculate; viral load in ejaculate; and presence of an STI

## HIV INFECTION

OraQuick, a rapid test (40-60 minutes) was approved by the FDA in November, 2002.
For entire guidelines see www.aidsinfo.nih.gov
Proper management of HIV infection involves a complex array of behavioral, pyschosocial, and medical services. This information should not be a substitute for referral to a health-care provider or facility experienced in caring for HIV-infected patients. Hotlines:

CDC AIDS Treatment Information Service.....1-800-HIV-0440 (1-800-448-0440)
e-mail to: atis@hivatis.org & www.hivatis.org
CDC AIDS Clinical Trials Information Service....1-800-TRIALS-A (1-800-874-2572)
e-mailto: actis@actis.org International....1-301-519-0459
*For general information and referrals to local facilities:*
CDC National AIDS Hotline.....1-800-342-AIDS (1-800-342-2437)
Spanish.....1-800-344-7432
CDC National AIDS Clearinghouse.....1-800-458-5231
CDC Division of HIV/AIDS Prevention.....www.cdc.gov/hiv
Post exposure prophylaxis PEP.....1-888-HIV-4911

***Pregnancy***: All pregnant women should be offered HIV testing as early in pregnancy as possible. Birthing facilities delivering women who may not have had prenatal HIV testing should make rapid HIV testing available 24/7. This recommendation is particularly important because of the available treatments for reducing the likelihood of perinatal transmission and maintaining the health of the woman. HIV-infected women should be informed specifically about the risk for perinatal infection. Current evidence indicates that 15%-25% of infants born to untreated HIV-infected mothers are infected with HIV; the virus also can be transmitted from an infected mother by breastfeeding. Zidovudine (ZDV) reduces the risk for HIV transmission to the infant from approximately 25% to <2% through use of antiretroviral regimens and obstetric intervention and by avoiding breastfeeding. Therefore, **ZDV TREATMENT SHOULD BE OFFERED TO ALL HIV-INFECTED PREGNANT WOMEN**. Most women in the U.S. now receive triple therapy during pregnancy not just ZDV. In the United States, HIV-infected women should be advised not to breast-feed their infants. In other countries, the reduced risk of death from malnutrition, diarrheal disease, or other infections may outweigh the risk of contracting HIV.

Insufficient information is available regarding the safety of ZDV or other antiretroviral drugs during early pregnancy; however, on the basis of the ACTG-076 protocol, ZDV is indicated for the prevention of maternal-fetal HIV transmission as part of a regimen that includes oral ZDV at 14-34 weeks of gestation, intravenous (IV) ZDV during labor, and ZDV syrup to the neonate after birth.

# EVALUATION & MANAGEMENT OF SEXUAL ASSAULT

**National Domestic Violence Hotline: 1-800-799-SAFE • www.ndvh.org**

**Engage Rape Crisis Services.** Have trained provider do the examination whenever possible. See SANE (Sexual Assault Nurse Evaluation), www.sane-sart.com

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**Legal:** Report to authorities if required by your state.
Contact child protective services if victim is a minor

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**Obtain informed consent before history, physical and treatment**

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**History:** circumstances of assault, whether victim had loss of consciousness (may want to test for rohypnol), date/time/location, use of weapons etc, specifics re: oral, vaginal or anal contact, penetration, ejaculation or condom use, areas of trauma, bleeding by victim or assailant, recent consensual sexual activity before or after assault including condom use, LMP, contraceptive use, use of drugs or alcohol, whether victim showered, changed clothing etc.

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**Physical exam:** document any trauma with photographs (and patient's consent). Woods lamp (UV) may help identify semen or other debris.
**Forensic exam** done with a special "evidence collection kit" includes victim's clothing, swabs of buccal mucosa, vagina, rectum, combed (and pulled) specimens form scalp and pubic hair, fingernail scrapings and clippings, blood sample etc. Assure proper chain of evidence to legal authorities. PE may also include specimens for pregnancy, HIV, Hep B, syphilis, sperm, BV, Trich, GC/CT and Herpes.

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**Treatment:** Offer emergency contraception. Empiric RX for STIs: ceftriaxone 125mg IM plus azithromycin 1g PO or doxycycline 100mg PO BID x 7 days. Metronidazole 2g PO x 1 dose. HEP B vaccine if not immune and consider anti-retrovirals to decrease risk of HIV infection. Advise to abstain from intercourse until prophylaxis therapy completed and consider condom use until follow-up serologic testing complete (6 months)

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**Follow-up:** Medical visit in 2 weeks. Ongoing psychosocial support and advocate services should be assessed. Do pregnancy test. Test for GC, CT, Trich and BV if woman declined prophylaxis or developed new symptoms or requests it. Follow-up tests for HIV and RPR at 6 weeks, 3 and 6 months